Sunshine Act Meetings

Federal Register
Vol. 57, No. 118
Thursday, June 18, 1992

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

U.S. COMMISSION ON CIVIL RIGHTS

DATE AND TIME: June 26, 1992, 8:00 a.m.

PLACE: Ralph Metcalfe Federal Office Building, 77 East Jackson Boulevard, Chicago, Illinois.

STATUS: Open to the Public.

June 26, 1992

I. Approval of Agenda
II. Approval of Minutes of May 22 Meeting
III. Announcements
IV. Update on Prospective Los Angeles Hearing
V. *Education Opportunities for American Indians in Minneapolis and St. Paul Public Schools*
VI. *Shelter Issues in New York, the New Fair Housing Amendments and Eastern New York Public Housing*
VII. Appointments to the Montana (interim), South Dakota, and Wyoming (interim) Advisory Committees
VIII. Staff Director's Report
IX. Future Agenda Items

Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact Betty Edmiston, Administrative Services and Clearinghouse Division (202) 376-8105, (TDD 202-376-8116), at least five (5) working days before the scheduled date of the meeting.

CONTACT PERSON FOR FURTHER INFORMATION: Barbara Brooks, Press and Communications, (202) 376-8312.

Dated: June 16, 1992.

Carol McCabe Booker,

General Counsel.

[FR Doc. 92-14513 Filed 6-16-92; 3:15 pm]

BILLING CODE 6335-01-M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11:00 a.m., Thursday, July 2, 1992.

PLACE: 2033 K St., NW., Washington, DC, 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254-6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92-14444 Filed 6-16-92; 12:49 pm]

BILLING CODE 6351-01-M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11:00 a.m., Friday, July 10, 1992.

PLACE: 2033 K St., NW., Washington, DC, 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254-6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92-14445 Filed 6-16-92; 12:49 pm]

BILLING CODE 6351-01-M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11:00 a.m., Friday, July 17, 1992.

PLACE: 2033 K St., N.W., Washington, D.C., 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254-6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92-14446 Filed 6-16-92; 12:49 pm]

BILLING CODE 6351-01-M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11:00 a.m., Friday, July 24, 1992.

PLACE: 2033 K St., N.W., Washington, D.C., 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254-6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92-14447 Filed 6-16-92; 12:49 pm]

BILLING CODE 6351-01-M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11:00 a.m., Friday July 31, 1992.

PLACE: 2033 K St., N.W., Washington, D.C., 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254-6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92-14448 Filed 6-16-92; 12:49 pm]

BILLING CODE 6351-01-M

FEDERAL ELECTION COMMISSION

DATE AND TIME: Tuesday, June 23, 1992, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.
Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.
Matters concerning participation in civil actions or proceedings or arbitration
Internal personnel rules and procedures or matters affecting a particular employee

DATE AND TIME: Thursday, June 25, 1992, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor.)

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes
Title 26 Certification Matters
Advisory Opinion 1992-16: Mr. Roy A. Vitousek, III on behalf of Nansay
Advisory Opinion 1992-17: Mr. Ken Mack on behalf of Du Pont Merck
Advisory Opinion 1992-21: Senator Moynihan
Administrative Matters

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Press Officer, Telephone: (202) 219-4155.

Delores Harris,

Administrative Assistant.

[FR Doc. 92-14517 Filed 6-16-92; 3:16 pm]

BILLING CODE 6715-01-M

FEDERAL HOUSING FINANCE BOARD

TIME AND DATE: 10 a.m. Wednesday, June 24, 1992.

PLACE: Board Room Second Floor, Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

PORTIONS OPEN TO THE PUBLIC: The Board will consider the following:

1. Monthly Reports
   A. District Banks Directorate
   B. Housing Finance Directorate

PORTIONS CLOSED TO THE PUBLIC: The Board will consider the following:

1. Approval of the May Board Minutes
2. Examination and Regulatory Oversight Report
3. Legislative/Strategic Discussion
   A. Strategic Plan
   B. Legislative Update
4. Los Angeles/Community Investment Program Update
5. FHL Bank System Conference—July 1, 1992

The above matters are exempt under one or more of sections 552b(c)(2), (8), (9)(A) and (9)(B) of title 5 of the United States Code. 5 U.S.C. 552b(c)(2), (8), (9)(A) and (9)(B).

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Executive Secretary to the Board, (202) 408–2837.

J. Stephen Britt,

Executive Director.

[FR Doc. 92–14412 Filed 6–15–92; 4:18 pm]

BILLING CODE 6725–01–M

FEDERAL HOUSING FINANCE BOARD

TIME AND DATE: 8:00 a.m. Wednesday, July 1, 1992.

PLACE: Park Ballroom C, The Park Hyatt Hotel, 24th and M Street, N.W., Washington, DC 20037.

STATUS: The meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The Finance Board will be hosting a conference of the Federal Home Loan Bank System. Matters to be considered are the following:

1. Housing Finance Economic Environment
2. Federal Housing Finance Board Strategic/Housing Legislative Plans for 1993
   A. Strategic Plan
   B. Housing Finance Profile
   C. Legislative Program
3. FHLBank System Financial Plan for 1993
   A. 1992 FHLBank System Financials in Review
   B. 1993 Financial Plan

The above matters are exempt under one or more of sections 552b(c) (9)(A) and (9)(B) of title 5 of the United States Code. 5 U.S.C. 552b(c) (9)(A) and (9)(B).

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Executive Secretary to the Board, (202) 408–2837.

J. Stephen Britt,

Executive Director.

[FR Doc. 92–14413 Filed 6–15–92; 4:18 pm]

BILLING CODE 6725–01–M

FEDERAL MARITIME COMMISSION

TIME AND DATE: 10:00 a.m., June 24, 1992.

PLACE: Hearing Room One, 1100 L Street, NW., Washington, DC 20573–0001.

STATUS: Part of the meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTER(S) TO BE CONSIDERED:

Portion open to the public:

1. Docket No. 90–23—Automated Tariff Filing and Information System—Consideration of comments.

Portion closed to the public:

1. Fact Finding Investigation No. 16, Fifth Report.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523–5725.

Joseph C. Polking,

Secretary.

[FR Doc. 92–14526 Filed 6–16–92; 4:01 pm]

BILLING CODE 6730–01–M

NATIONAL CREDIT UNION ADMINISTRATION

Notice of Previously Held Emergency Meeting

TIME AND DATE: 10:10 a.m., Monday, June 15, 1992.

PLACE: Filene Board Room, 7th Floor, 1776 G Street, NW., Washington, DC 20456.

STATUS: Closed.

MATTERS CONSIDERED:

1. Administrative Action under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
2. Personnel Actions. Closed pursuant to exemptions (2) and (6).

The Board voted unanimously that Agency business required that a meeting be held with less than the usual seven days advance notice.

They voted unanimously to close the meeting under the exemptions listed above. Deputy General Counsel James Engel certified that the meeting could be closed under those exemptions.

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (202) 682–9600.

Becky Baker,

Secretary of the Board.

[FR Doc. 92–14442 Filed 6–16–92; 12:48 pm]

BILLING CODE 7535–01–M

NATIONAL CREDIT UNION ADMINISTRATION

Notice of Meetings

TIME AND DATE: 9:30 a.m., Tuesday, June 23, 1992.

PLACE: Filene Board Room, 7th Floor, 1776 G Street, NW., Washington, DC 20456.

STATUS: Open.

BOARD BRIEFINGS:

1. Central Liquidity Facility Report and Report on CLF Lending Rate.
2. Insurance Fund Report.
3. Progress Report—NCUA's Long Range Plan.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Open Meeting.
2. NCUA's Long Range Plan—FY 1993–1997.
3. Proposed Rule: Amendment to Part 702, NCUA's Rules and Regulations, Reserves.
4. Final Rule: Amendment to Part 722, NCUA's Rules and Regulations, Appraisals.

TIME AND DATE: 11:00 a.m., Tuesday, June 23, 1992.

PLACE: Filene Board Room, 7th Floor, 1776 G Street, NW., Washington, DC 20456.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Closed Meeting.
2. Request from State for Exemption from Section 701.21(h), NUCA's Rules and Regulations. Closed pursuant to exemptions (4), (8), (9)(A)(ii), and (9)(B).
3. Central Liquidity Facility Line of Credit. Closed pursuant to exemptions (4) and (9)(A)(ii).

4. Appeal under Parts 701 and 747, NCUA's Rules and Regulation. Closed pursuant to exemptions (8) and (9)(A)(ii).

5. Administrative Action under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).

6. Proposed National Corporate Credit Union Program. Closed pursuant to exemptions (2), (8), and (9)(B).

7. Delegations of Authority. Closed pursuant to exemptions (2) and (9)(B).

8. Conversion under Part 708, NCUA's Rules and Regulations. Closed pursuant to exemptions (8) and (9)(A)(ii).

9. FY 1992 Budget Reprogramming. Closed pursuant to exemptions (2) and (9)(B).

10. Personnel Actions. Closed pursuant to exemptions (2) and (6).

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (202) 682–9600.

Becky Baker,

Secretary of the Baord.

[FR Doc. 92–14443 Filed 6–16–92; 12:48 pm]

BILLING CODE 7535–01–M

federal register

Thursday
June 18, 1992

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 405, 420, 421 and 424
Medicare Program; Criteria and Standards for Evaluating Regional Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); Final Rule and Request for Comments

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 420, 421 and 424

[BPO-102-FC]

RIN 0938-AF59

Medicare Program; Carrier Jurisdiction for Claims for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues Involving Suppliers, and Criteria and Standards for Evaluating Regional DMEPOS Carriers

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule—

- Modifies regulations to provide that claims for durable medical equipment, prosthetics, orthotics and certain other items covered under part B of Medicare be processed by designated carriers.
- Specifies the jurisdictions each designated carrier will serve.
- Changes the method by which claims for these items are allocated among the carriers from "point of sale" to "beneficiary residence."

Establishes certain minimum standards for suppliers for purposes of submitting the above claims.

Incorporates in regulations certain supplier disclosure requirements imposed under section 4164 of the Omnibus Budget Reconciliation Act of 1990, as part of the process for issuing and renewing a supplier's billing number. Describes the criteria and standards to be used beginning October 1, 1993 for evaluating the performance of designated carriers processing claims for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in the administration of the Medicare program. Section 1842(b)(2) of the Social Security Act requires us to publish criteria and standards against which we evaluate Medicare carriers for public comment in the **Federal Register.**

We expect the above changes to lead to more efficient and economical administration of the Medicare program.

DATES: These regulations are effective August 17, 1992 with the exception of § 424.57(f) that imposes information collection and record keeping requirements subject to the Paperwork Reduction Act.

Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 17, 1992.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPO-102-FC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your written comments to one of the following addresses: Room 308-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

In commenting, please refer to file code BPO-102-FC. Written comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in room 309-G of the Department's office at 200 Independence Ave., SW., Washington, DC on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

If you wish to submit comments on the information collection requirements contained in this final rule with comment, you may submit comments to: Allison Herron Edyt, HCFA Desk Officer, Office of Information and Regulatory Affairs, room 3002, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Lisanne Bradley, (410) 966-3359, for carrier jurisdiction for claims for durable medical equipment, prosthetics, orthotics and supplies, and other issues involving suppliers.

Larry Pratt, (410) 966-7403, for criteria and standards for evaluating designated carriers processing durable medical equipment, prosthetics, orthotics, and supplier claims.

SUPPLEMENTARY INFORMATION:

I. Background

Under sections 1816(a) and 1842(a) of the Social Security Act (the Act), public and private organizations and agencies may participate in the administration of the Medicare program under agreements or contracts entered into with HCFA (acting on behalf of the Secretary of HHS). These Medicare contractors are known as fiscal intermediaries (section 1816(a) of the Act) and carriers (section 1842(a) of the Act). Intermediaries primarily perform part A bill processing and benefit payment functions, and carriers perform part B claims processing and benefit payment functions. Section 1842(a) of the Act authorizes contracts with carriers for the payment of claims for Medicare covered services and items. The statute does not place any restriction on the area which any carrier must serve. Consequently, we have contracts for carriers to process claims in areas that are multi-State, State-wide, or lesser areas.

Our experience has been that there is diversity among carriers in their interpretation of coverage policies, local medical review policies, and pricing for similar items and services. To some extent a carrier's performance is affected by the nature of its workload. That is, the more unusual a piece of equipment or supply is in an area, the more difficult it is to make a coverage or pricing determination. To the extent that carrier determinations reflect local norms, diversity is desirable, but to the extent that local norms result in unwarranted variations in payment amounts, utilization parameters, or claims documentation policies for items furnished nationally, such diversity is undesirable.

Claims for DMEPOS are submitted by suppliers. The term "supplier" is defined in our regulations at 42 CFR 400.202 as a physician or other practitioner, or an entity other than a "provider", that furnishes health care services, including items, under Medicare. A "provider" as defined in § 400.202 means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement to furnish outpatient physical therapy or speech pathology services (see sections 1861(u) and 1866(e) of the Act). In practice, an entity, including a provider, that wishes to become a supplier to Medicare beneficiaries does so merely by issuing bills for Medicare covered items and services. Most carriers require some identifying information from a supplier before it receives a billing number, but there are no national requirements that a DMEPOS supplier must meet. The absence of a well-defined process for issuing supplier numbers and the diversity in handling claims have resulted in some abuses under the Medicare program by some entities that hold themselves out to be suppliers. Some suppliers exploit current carrier jurisdiction policies by submitting claims only to those carriers whose claims review policies result in more inclusive or expansive determinations of Medicare coverage or in higher payment amounts, for the items they supply.

Section 1834(a)(12) of the Act authorizes the Secretary to designate, by regulation under section 1842 of the Act, one carrier for one or more entire regions to process all claims within the region for certain covered items. When read in conjunction with sections 1834 (a)(13) and (h)(3), the covered items include all covered durable medical equipment, prosthetics, prosthetic devices, and orthotics. Other items for which claims may be processed by regional carriers include: Home dialysis supplies and equipment; surgical dressings; splints, casts, and other devices used for reduction of fractures and dislocations; immunosuppressive drugs; parenteral and enteral nutrients, equipment and supplies; and other items, including those provided by a physician for which separate payment is appropriately made outside the Medicare physician fee schedule, but not those items covered "incident to" a physician's service or bundled into a facility payment.

II. Notice of Proposed Rulemaking

On November 6, 1991 we published a proposed rule (NPRM) with a 60-day comment period (56 FR 56612) that would amend 42 CFR parts 400, 420, 421 and 424. Specifically, the rule proposed to change 42 CFR part 421, Intermediaries and Carriers, to allocate DMEPOS claims among carriers based on beneficiary residence. In the preamble to that NPRM we proposed that we would choose four carriers nationally that would each process an approximately equal number of claims. The concentration of claims processing would achieve economies as well as consistency of processing within each designated area. The area boundaries would coincide with those of existing Common Working File (CWF) sectors (which store data on Medicare beneficiaries residing within the area). We also proposed that the responsibility for processing claims for beneficiaries residing within each regional area would be allocated to the regional carrier for that area.

We proposed the types of criteria to be used for designating these carriers which would include experience in processing DMEPOS claims and establishing DMEPOS local medical review policy and pricing, quality, timeliness and processing cost per claim.

We proposed to establish in 42 CFR part 424, certain minimum standards for entities seeking to qualify as suppliers. In order to obtain a Medicare billing number, an entity would be required to meet, and to certify that it meets, a number of supplier standards. A supplier must receive and fill orders for DMEPOS from its own inventory or inventory in other companies with which it has contracted to fill such orders. In addition, a supplier must be responsible for delivering Medicare covered items to Medicare beneficiaries or arranging for their delivery to an outlet convenient to the beneficiary, honoring any warranties, answering any questions or complaints the beneficiaries might have, maintaining and repairing rental items and accepting returns of substandard or unsuitable items from beneficiaries. We also proposed that each supplier must maintain a complaint log.

We proposed a number of changes to 42 CFR part 420, which concerns Medicare program integrity. To improve out ability to curtail abusive practices on the part of some suppliers, we proposed to require a supplier to furnish ownership and control information. These requirements would implement the reporting requirements in section 1124A of the Act, as enacted by section 4164(b) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90).

We proposed to make several clarifying or conforming changes. We would—

Delete the definition of "supplier" in § 420.201 as it is unnecessary for program integrity purposes and conflicts with the definition in part 400.

Add the requirement that any physician with a Unique Physician Identification Number (UPIN) provide that number. This is now our most consistently used physician identifier.

Add a requirement that suppliers must report changes in ownership or control within 180 days. This would make our requirement consistent with provisions of section 1124A of the Act, as revised by OBRA 90.

Revise the definition of "disclosing entity" to include a part B supplier.

III. Analysis of and Responses to Public Comments, and Revisions to the Proposed Rule.

In response to the November 6, 1991 proposed rule, we received 42 timely items of correspondence. Comments were submitted from Medicare carriers, various associations and organizations representing facilities and suppliers, medical and other professional individuals, and law firms. A summary of individual comments and responses, and summarized changes, if any, to our rule are discussed below:

Effective Date

Comment: Two commenters were apprehensive that if pending legislation, which contains similar, but not identical, provisions to those of this regulation were passed, it would impede implementation of these amendments of the regulations. They suggested that we wait until legislation is passed before proceeding. One commenter thought that legislative authority would give more weight to some of our changes.

Response: Our plans for this regulation preceded any of the proposed legislation, and we expect that this regulation will be published in the **Federal Register** before any new legislation can be promulgated. Most of the provisions of the proposed legislation are generally consistent with what we are trying to achieve in this regulation, so if legislation is passed, we believe it will only strengthen the authority we already have to make these changes.

Regionalization

Comment: There was a general consensus from the commenters that regionalization of claims processing for DMEPOS items was desirable for the reasons mentioned in the proposed rule.

Response: We appreciate the support we have received for regionalization of claims processing for DMEPOS items.

Comment: One commenter expressed concern that success with the parenteral and enteral nutrition (PEN) specialty carriers was no reason to believe that there would be similar success with DMEPOS claims due to the much larger number of claims. Several commenters from the orthotic and prosthetic, PEN and home dialysis supply industries preferred that special arrangements be made for processing their claims.

Response: We believe that the processing of DMEPOS claims is significantly different from that of claims for medical services. We do not, however, see that there is a significant difference in the system used to process claims for different types of medical items. It is true that each type of DMEPOS is subject to its own coverage, utilization and documentation requirements, but medical review to determine whether a particular DMEPOS item is medically necessary follows essentially the same process for all such items.

Regionalization allows us to pool sufficient numbers of each type of claim so that carrier staff, including fair hearing officers; can be proficient in its review. No type of DMEPOS item is so rare that there will not be a sufficient number of claims at each of the four regional carriers to develop this expertise. While even greater expertise could be developed if certain types of claims were sent to only one or two

carriers, as is currently done with PEN claims, we cannot justify the higher average processing costs that are inevitable when a smaller number of claims are separately processed. We continue to believe that the designation of four carriers to process claims for all types of medical items continues to be the most feasible answer to the problems we have recently experienced with these claims. We note that the four regional carriers will assure that face-to-face fair hearings are conducted throughout their regions.

Comment: One commenter wanted a single carrier to process claims, while another commenter preferred that we consider establishing fewer than four regional carriers. Another suggested 10 regional carriers, one for each HCFA administrative region.

Response: Our major concern in establishing the number of regional carriers was that there be few enough to allow the carriers to develop medical review and pricing expertise for all types of Medicare part B covered items, but enough that each carrier would receive a manageable workload, i.e., about 6–7 million claims. We believe that four regional carriers best meet HCFA's needs for increased claims processing expertise and eoncomical and efficient processing.

The areas chosen as DMEPOS regions divide the national DMEPOS workload into approximately equal parts and conform to the areas established by CWF sector boundaries. Having the DMEPOS regions coincide with CWF boundaries is efficient because it minimizes the number of out of area claims to be processed. Out of area claims are more expensive to process. We also considered the number of suppliers in each area and the location of major metropolitan areas located on CWF boundaries.

Comment: A few comments were received on the configuration of the regions. One commenter suggested that if each of the regional carriers were linked to all CWF host sites, there could be a reconsideration of the boundaries described in the proposed regulation. Other commenters suggested that we choose our carriers first and then configure our regions around the carriers.

Response: We have decided to issue a competitive request for proposals for the regional carrier contracts. In order to effectively bid for these contracts, the offerors must know the number of claims and the area for which they are bidding. Therefore, we affirm the boundaries of the four regions specified in the proposed regulation.

Competitive Bidding

Comment: Most commenters agreed that the regional carriers should be determined as a part of a competitive procurement process.

Response: We have the authority either to select non-competitively carriers under section 1842 of the Act, or to procure the contracts competitively. We have chosen to use a competitive procurement this time. We have issued a Pre-Solicitation Notice for Comment which will be followed by a Request for Proposals (RFP).

Timely proposals will be accepted from all offerers which meet the definition of "carrier" in section 1842(f) of the Act: "* * * a voluntary association, corporation, partnership, or other nongovernmental organization which is lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier, including a health benefits plan duly sponsored or underwritten by an employee organization * * *."

Criteria for Designation of Contractors

Comment: Several commenters expressed a great deal of interest in the criteria which HCFA would use to designate the four regional carriers. Of the four definite criteria listed in the proposed regulation, there was general agreement that they should all be factors in designation. Some commenters expressed some concern that cost might be treated as the overriding factor and actually put our current PEN carriers at a competitive disadvantage. There was also concern that two much reliance would be placed on Contractor Performance Evaluation Program (CPEP) data, since it reflects carrier overall performance and does not focus on a carrier's ability to process the 5 percent of its claims which are for DMEPOS. Most commenters specified indicia for judging that the four criteria were met or added other criteria. One of the commenters wanted to know the weights that would be applied to each of the criteria. Most commenters wanted the final criteria published in the **Federal Register.**

Response: We published the abbreviated criteria for carrier selection in the proposed regulation to notify the public of the general parameters we intended to use for either a selection or procurement of regional carriers. More specific criteria as well as the weights for those criteria will be included in the RFP.

Many excellent ideas for criteria were presented. We will seriously consider the criteria suggested by commenters for inclusion in the RFP, but we do not plan to publish those specific criteria in the **Federal Register.** That type of detailed information is more appropriate for inclusion in procurement documents, such as the RFP. After the initial contract period we may wish to change our emphasis and publish new criteria. However, we are including the general criteria in the regulation to make clear HCFA's intent to designate regional carriers with experience in claims processing to process claims with quality and timeliness, at a reasonable price.

Comment: Some of the commenters wanted suppliers, and associations representing them, to have a role in the selection of the regional carriers.

Response: It is not permissible to involve suppliers or their representatives in a competitive government procurement which is subject to the Federal Acquisition Regulations.

Regional Carrier Contract

Comment: One commenter believed that the regional carrier contracts should be totally separate and distinct from any other contracts the carrier might have with HCFA.

Response: We agree and will be executing separate contracts for the DMEPOS regional carriers. Pertinent portions of the proposed contract have been published with the Pre-Solicitation Notice. The DMEPOS regional carrier statement of work will also be included in the contracts.

Transition and Implementation

Comment: A large number of commenters expressed concern about the delays in payments which occurred in previous carrier transitions. Some commenters stated that a system for advance payments should be established for this transition.

Response: HCFA is committed to an orderly transition process which does not cause undue delays in payment. The details of that plan have been published in the Pre-Solicitation Notice. Comments on that notice have been received and are being analyzed before the RFP is published. We do not believe a special procedure for advance payments will be necessary, but we are developing general guidelines as to when advance payments will be appropriate for all carriers. The DMEPOS regional carriers

will follow the same procedures as all other carriers.

Comment: Several commenters thought some sort of phase-in would be appropriate. Most of the commenters preferred a phase-in by type of DMEPOS, and one commenter suggested a phase-in by States.

Response: An integral part of implementation will be a phase-in plan. We considered phasing-in by type of equipment, type of beneficiary, type of supplier, etc., but determined that phase-in on any of those criteria would cause some suppliers to be billing both regional and local carriers for an interim period. The plan we have chosen will first phase-in suppliers which operate in more than one State and which choose "early boarding," that is, to begin submitting all their DMEPOS claims to the regional DMEPOS carriers in the first month, and those that submit claims for Railroad Retirement beneficiaries, since the Railroad Retirement Board has agreed to contract with the four DMEPOS regional carriers for the processing of DMEPOS claims. As a result, suppliers will no longer need to obtain separate billing numbers for their Social Security and Railroad Retirement Medicare beneficiaries. During subsequent months of the four month implementation period, we will phase in claims State-by-State for claims currently being processed by the carriers located in each State. Under our current schedule, PEN claims will be phased-in at the same time as the other DMEPOS claims processed by Blue Cross and Blue Shield for South Carolina and Transamerica Occidental Life Insurance Company, unless PEN suppliers choose "early boarding" during the first month of implementation. The exclusive use of beneficiary residence for determining claims jurisdiction is required for the regional DMEPOS carriers only. During the implementation period, "point of sale" will continue to be used as the jurisdiction policy for DMEPOS claims processed at local carriers and "home office" claims jurisdiction policy for PEN claims processed by the two PEN specialty carriers.

Comment: Commenters placed emphasis on the need for education about the procedures to be used by the regional carriers for beneficiaries, physicians, suppliers and local carrier personnel.

Response: We agree. Education is an integral part of the transition plan published in the Pre-Solicitation Notice.

Comment: One commenter suggested that sufficient funding be allocated to the local carriers to assure that they provide the regional DMEPOS carriers with the support they need for a successful transition.

Response: We do not anticipate any problems resulting from less than full cooperation from the local carriers. Unlike transitions in the past, the local carriers will continue to be under contract with HCFA and process all other types of claims. Cooperation with the transition effort will be considered critical and will be evaluated as part of the total contractor evaluation.

We do not believe that some of the specific expected transition problems mentioned by commenters will exist. For example, we do not plan to require transfer of claims history or medical necessity documentation files from the local carriers to the regional DMEPOS carriers. Instead, we currently plan to have the regional carriers rely on CWF which will collect this information and make it an integral part of the query process, rejecting duplicate claims, ascertaining the existence of current medical necessity documentation, alerting questionable situations, etc. The files which local carriers must transfer, such as pricing data, will be transferred early in the transition period and can be tested rigorously before the "live" date.

Comment: Several commenters suggested that we first consolidate the non-PEN claims at the regional carriers; then, move the PEN claims.

Response: As mentioned above, we do not currently plan on moving the PEN claims after transition of other types of claims. We view these claims, with their one national pricing locality and well-established coverage policy and utilization parameters, as the claims which will be easiest for the new regional carriers to absorb.

Comment: One commenter suggested that administration of the regional carriers, at least on an interim basis, ought to be centered in HCFA's central operations, rather than in the regional offices, to assure timely and comprehensive resolution of any transition problems.

Response: Both the central and regional offices of HCFA will have integral roles in the monitoring of the transition. After operations at the regional carriers have stabilized, the four regional offices parallel to the regional carriers will assume primary operational responsibility for the regional carriers.

Evaluation of Regional Carriers

Comment: Commenters generally were in favor of a separate evaluation program for the regional carriers. The critieria they suggested for inclusion in that evaluation were very similar to the criteria they suggested for selection of the regional carriers.

Response: We agree that a separate evaluation of DMEPOS functions should be performed at the regional carriers, even if those carriers have other Medicare contracts. We have considered the many, excellent ideas presented by all commenters. The criteria for evaluation which we believe best address HCFA needs are included later in the preamble of this final rule, and we invite comment.

Claims Jurisdiction Policy

Comment: Most commenters agreed that using "point of sale" to determine carrier jurisdiction for processing claims for DMEPOS had served its purpose and that it was time to establish another policy. A few commenters suggested that there would be no need to change jurisdiction policy if we established pricing, coverage policy and utilization parameters on a national basis. A few commenters preferred using "point of delivery" as the point of reference for claims jurisdiction policy.

Response: We have thoroughly examined all possible bases for determining carrier claims processing jurisdiction. "Point of delivery" was analyzed when a component within the Department of Health and Human Services suggested that HCFA consider it. Our analysis concluded that in border areas, point of delivery could be manipulated by requiring beneficiaries to pick up their purchases or rentals from a location within the higher priced area. "Point of delivery" would be more expensive for HCFA to administer, since the claim histories for most beneficiaries are housed on the CWF host local to their permanent address. Under the current system, some suppliers have forced beneficiaries to call out of area offices to obtain items stored locally. We want to return to a system where beneficiaries have a choice of purchasing items their physicians find medically necessary for them, locally or from an out-of-State supplier. Whatever supplier the beneficiary chooses, the beneficiary's claim will be subject to the same carrier's regional coverage guidelines and the same State-wide payment rates, based on the site of the beneficiary's permanent address.

Comment: Several commenters requested exceptions to using beneficiary residence to determine carrier jurisdiction for beneficiaries living within a 60 mile radius of a border, those obtaining medical care in a tertiary care facility, and beneficiaries who are traveling or who have two homes.

Response: Exceptions to the beneficiary residence rule would not be appropriate, since one of the major intentions of these changes is to establish beneficiary specific records in the regional carrier within whose area a beneficiary has a permanent residence. Exceptions to the rule will result in the type of system we currently have where claims for a beneficiary may be processed anywhere in the country. No matter where borders are drawn there will be suppliers, which service a limited market area, that will be disadvantaged by having to submit claims to more than one regional carrier. Of course, there will be many fewer carriers, so that many claims for the exceptions cited above will actually be submitted to the same regional carrier. We have drawn the borders of the four regions to avoid, as much as possible, major metropolitan areas located on State borders, while conforming to the CWF sections.

Comment: Several commenters expressed concern about how a supplier was to determine the "legal address for tax purposes of a beneficiary," as required by the proposed rule.

Response: Concern about how to determine a beneficiary's legal address for tax purposes has led us to change the terminology to "permanent residence." Permanent residence is defined as the address at which a beneficiary intends to spend over six months of the calendar year. When a beneficiary moves to another address with the intent to stay at that address for over six months of the calendar year, then that address becomes the permanent residence. Thus, only the beneficiary can designate his/her permanent residence. A supplier must obtain permanent residence information from its customer, the Medicare beneficiary or his/her authorized representative.

A regional carrier will pay the rate applicable for the address shown on a claim unless it has reason to believe that the address is incorrect. If there is a question as to the correct permanent address, the regional carrier will conduct an investigation to determine the correct permanent address for the beneficiary.

Comment: One commenter suggested that the regional carrier be responsible for the determination of beneficiary residence or that suppliers be given access to the CWF to verify legal residence.

Response: There will be no need for the carriers to track beneficiary residence, except where there is evidence of abuse by a supplier. Likewise, suppliers will not need to verify, with the carrier or the CWF, the permanent residence of a beneficiary.

Issuance of Supplier Numbers

Comment: Commenters generally supported the supplier number issuance process. It was noted that the process is "akin to a license."

Response: The commenter is not correct in comparing the issuance of a supplier number to a license. A DMEPOS supplier can still furnish items to individuals other than Medicare beneficiaries, even if it is not approved for Medicare billing. However, if an entity meets the Medicare supplier standards it is a "supplier" and, therefore, eligible to receive Medicare payments or to have beneficiaries reimbursed for purchases or rentals it makes to them.

Comment: A few commenters preferred that suppliers be accredited or certified in a fashion similar to that used under Part A of Medicare, rather than the supplier numbering process we proposed.

Response: The certification process is authorized by statute for providers and certain suppliers, but not for DMEPOS suppliers. In general, that process is reserved for entities that furnish direct patient care and would not be appropriate for suppliers of items. We think it is appropriate, however, to require that entities which sell DMEPOS items to Medicare beneficiaries meet certain minimum business requirements in order to be recognized as Medicare suppliers.

Comment: A few commenters suggested that stating that we would reissue supplier numbers every two to three years did not give suppliers the certainty they need to plan adequately. It was also suggested that the supplier number re-issuance process be limited to suppliers in noncompliance with HCFA requirements. Another commenter thought that the process would be costly and an administrative nightmare, with little positive results. It was suggested that an annual purge of billing numbers which had not been used during the previous twelve months would avoid the problem of having defunct entities with supplier numbers.

Response: We agree that the two to three year language is ambiguous. We intend to require that suppliers reapply for supplier numbers every three years. For suppliers initially issued numbers in 1993, however, we will require about one-third of the suppliers to reapply for numbers two year later. In the third year we will require that another third of all suppliers reapply for supplier numbers and in the fourth year require the final third of suppliers to reapply. Supplier numbers issued in any of those years will not be subject to renewal for another three years. However, if no claims are submitted by a DMEPOS supplier over a period of four consecutive quarters, the supplier will also be asked to reapply for a supplier number. This process is intended to assure that only active suppliers have billing numbers. We plan to minimize cost and administrative effort for both the regional carriers and suppliers by providing to each supplier reapplying for a supplier number a copy of its current enrollment information and having the supplier check the information, make any necessary corrections and recertify that supplier standards are being met and that all ownership information is correct.

Comment: Several commenters stated their need for multiple supplier numbers for different addresses or product lines to aid in their accounting controls.

Response: We agree that for accounting purposes it is reasonable for suppliers with more than one business outlet to be allowed more than one billing number, in the form of a basic supplier number followed by a modifier. We do not agree to allow multiple numbers for multiple product lines, since a supplier can easily determine the amounts paid for each product line using the HCPCS codes.

Comment: One commenter requested that it be allowed to apply for billing numbers for all of its branch offices at one time.

Response: We would prefer that a supplier with multiple outlets submit supplier number application forms for all of it branches at the same time. Large suppliers should find this convenient, since only information on the addresses and managing employees, including any past or current associations with other suppliers and any sanctions they may have received, would differ.

Comment: We also received comments about implementation which emphasized the need for us to allow ample time for processing applications and obtaining any necessary additional or clarifying information. One carrier commented that it would be better to implement the disclosure statute in concert with the implementation of the regional carriers.

Response: We agree that sufficient implementation time is critical. We plan to collect supplier address information from all carriers this year and mail instructions and enrollment forms to all current suppliers. These forms will be returned to a single National Supplier Clearinghouse, one of the four regional carriers. New billing numbers should be

issued to DMEPOS suppliers approximately 2 months before claims are first processed by the regional carriers. The new numbers will not be used at local carriers.

Disclosure of Ownership

Comment: One commenter felt that the requirement proposed in § 420.206(b)(3) to provide updated information only 180 days after a change in ownership, etc., was too liberal.

Response: We agree. Although section 1124A(b) of the Act provides that a supplier must update ownership information within 180 days after a change, we believe that we have the authority to shorten the period, in the interest of effective implementation of the statute, and especially in light of our need to make correct payment decisions. We are revising § 420.206(b)(3) by shortening that period to 35 days to coincide with that for requested information.

This change would make the period for disclosure of changes the same as the period for response to requests for ownership information. Because of the problems we have experienced with fraudulent and abusive suppliers, the regional carriers will need to track closely changes in ownership to assure that suppliers related to problem suppliers are also closely scrutinized.

Comments: Several commenters requested a more precise definition of "control interest" and "managing employee." Some commenters suggested that we limit managing employees to those with ownership interests or that we use a standard commercial law definition. One commenter asked that specific ownership information on companies publicly traded on a major exchange be limited to those with a 10 percent or more interest.

Response: Section 1124A of the Act specifies the requirements for disclosure of ownership and defines "person with an ownership or control interest" as (1) a person described in section 1124(a)(3) of the Act or (2) a person who has one of the 5 largest direct or indirect ownership or control interests in a supplier. Section 1124(a)(3) defines "person with an ownership or control interest" as "a person who (A)(i) has directly or indirectly (as determined by the Secretary in regulations) an ownership interest of 5 per centum or more in an entity; or (ii) is the owner of a whole or part interest in any mortgage, deed or trust, note, or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 per centum of the total property and assets of the entity; or (B) is an officer or director of the entity, if the entity is organized as a corporation; or, (C) is a partner in the entity, if the entity is organized as a partnership." We also believe that "control interest" includes any person meeting the above definitions for an entity which is involved in a joint venture which is seeking to qualify as a supplier and receive a billing number. Most of this definition is repeated in 42 CFR 420.201, published in 44 FR 41642, July 17, 1979, under the definition of a "person with an ownership or control interest." We will amend the definition in the regulations to bring it completely into accord with the above definition. The above definition makes clear that we cannot adopt the suggestion to limit reporting to those with a ten percent interest.

"Managing employee" is defined in section 1124A of the Act as a person described in section 1126(b) of the Act. Section 1126(b) defines "managing employee" as "an individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity." This definition is repeated in 42 CFR 420.201 and needs no amendment.

Comments: One commenter asked that we not include criminal offenses against title XX of the Act, pertaining to the Social Services Block Grant program, in our definition of reportable criminal offenses. Another requested that only histories of administrative sanctions, i.e., multiple offenses, by managing employees be reportable.

Response: Section 1124A(a)(2) of the Act also requires disclosure of any administrative sanctions, i.e., "penalties, assessments or exclusions" which have been assessed against any person with an ownership or control interest or a managing employee under section 1128, 1128A or 1128B of the Act. Those sections deal, respectively, with mandatory an permissive exclusions, civil monetary penalties, and criminal penalties for acts involving Medicare or State health care programs. Section 1128(h) defines a "State health care program" as (1) a State health plan approved under title XIX of the Act (Medicaid), (2) any program receiving funds under title V (Maternal and Child Health Services Block Grant Program), or from an allotment to a State under such title or (3) any program receiving funds under title XX or from an allotment to a State under such title. Thus, we must include convictions for criminal offenses under title XX of the Act in the information to be reported. We also cannot agree that only "histories" of administrative sanctions be reported, when the statute is clear that any such instance must be reported.

Application of Disclosure of Ownership Requirements to Suppliers not Accepting Assignment

Comment: Two commenters questioned HCFA's authority to expand disclosure of ownership requirements to suppliers not accepting assignment. Another praised HCFA for extending the requirements.

Response: Section 1833(e) of the Act gives HCFA the general authority to obtain any information it needs to correctly pay part B claims. We believe that this authority extends to ownership information, which can be relevant in determining whether there are outstanding overpayments for individuals involved with a supplier. We also believe that the disclosure provision in section 4164(b) of OBRA 90 also provides authority, as specified in section 1124A of the Act, to request information from all suppliers. The statute states that "* * * no payment may be made for items or services furnished by any disclosing part B provider unless such provider has provided the Secretary with full and complete information * * *" A "disclosing part B provider" means any entity receiving payment on an assignment related basis for furnishing items * * *" Even suppliers which do not "participate," i.e, agree to always accept assignment, may accept assignment on any claim. The statute does not require that more than one assigned claim be presented, but does require that full disclosure be made prior to payment of that claim. Therefore, it is reasonable to require disclosure routinely from all suppliers. It is also much more administratively efficient, since over 90 percent of all DMEPOS claims are, indeed, assigned.

We are also making disclosure a supplier standard. All entities must attest that they have made full and accurate disclosure in order to qualify as a Medicare supplier and to obtain a billing number.

National Database of Supplier Information

Comment: One commenter recommended a national supplier database to assemble and analyze relationships among suppliers.

Response: We agree. As mentioned above, we plan to designate one of the regional carriers as a National Supplier Clearinghouse. That carrier will process all supplier number applications, house files on all suppliers, including

ownership and other information collected on the HCFA–192, and correlate that information routinely, so that each regional carrier can annotate its files. It will also assist in special studies conducted by the regional carriers, HCFA or the DHHS Office of Inspector General (OIG).

Supplier Standards—General

Comment: There was general agreement that standards need to be set for suppliers. Several commenters thought that these standards ought to be quality, rather than business oriented, and more like the survey and certification process for Part A providers.

Response: As stated above, we do not want to establish quality of service standards for DMEPOS suppliers, since we can not pay suppliers for direct patient care, but can only pay for items and, in certain circumstances, maintenance, servicing, and repair. HCFA does have the responsibility and the authority to determine correct payment amounts and to ascertain that we are paying the correct suppliers. In order to assure we are paying the correct supplier, we must collect ownership information. We further have a responsibility to Medicare beneficiaries to assure that suppliers meet certain minimum business standards.

Comment: One commenter thought that certification as a part A provider ought to obviate the need for meeting the part B supplier standards.

Response: Since the part B supplier standards do not measure the same factors as the certification process, provider status will not automatically qualify the provider as a supplier. Any provider or physician who sells or rents items to a Medicare beneficiary for which a part B claim will be submitted to a DMEPOS regional carrier, must qualify as a supplier in order to be paid for those items.

Comment: One commenter felt that self-certification seemed ineffective and recommended that, at least, random validation would be necessary.

Response: We believe that self-certification is sufficient for almost all suppliers, especially since a false report to the government could constitute a serious offense. The regional carriers will investigate suppliers with which we experience problems and about which we received complaints.

Comment: Another commenter thought that while the idea of standards was admirable, these particular standards impede a supplier's ability to maintain business flexibility and result in excessive paperwork.

Response: We do not believe that the minimum standards proposed for suppliers will limit their business flexibility. We are adding a new § 424.57 Special payment rules for items provided by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers, to clear up any misunderstandings there may be. We address these changes below, when we answer comments on specific standards. The paperwork associated with supplier standards, except for the complaint log, which is discussed below, consists of signing a certification that the standards are being met, usually only once every three years, and distributing copies of the supplier standards to Medicare customers.

Inventory Requirements

Comment: A few commenters were concerned about the requirement that suppliers fill orders from their own inventories or from inventory in companies with which they have contracted. The suppliers of prosthetics and orthotics were especially concerned since they maintain no inventory, but rather, custom fabricate items for each of their patients.

Response: We agree that we need to address the situation of the suppliers of prosthetics and orthotics. We specify in the requirement in new § 424.57(c)(1) the phrase: "or fabricates or fits items for sale from supplies it buys under a contract." The contracts referred to in this phrase and in the "inventory in other companies" need not be detailed written contracts, but they should be objectively provable. This provision is designed to exclude entities which merely act as brokers for other suppliers.

Delivery

Comment: Several commenters wanted clarification on the meaning of "delivery."

Response: Delivery does not necessarily mean delivery to the beneficiary's home. It also includes direct delivery to a beneficiary or his/her representative in the supplier's place of business. What we are trying to address with this provision are suppliers which accept orders from beneficiaries and then sell those orders to another company. This provision affirms that the supplier which accepts the order from the beneficiary has the responsibility to assure that the beneficiary receives what is ordered and that the supplier is responsible if the order is not received or is substandard or unsuitable.

Warranties

Comment: A number of commenters requested that we more narrowly define "warranties" as either those defined under the Uniform Commercial Code, under applicable State law or as "express and implied."

Response: We agree that further clarification is needed. In new § 424.57(c)(3), we clarify that "warranties" means "all warranties express and implied under applicable State law."

Comment: One commenter questioned how this provision would apply to customized devices and "service intensive treatments."

Response: Warranties for customized devices will be those applicable under State law for a completed device (materials and labor) as furnished to a Medicare beneficiary. "Service intensive treatments" are not reimbursable under any of the DMEPOS benefits.

Answers Questions and Complaints

Comment: One commenter recommended that we limit this standard to questions pertinent to the item being provided and not require suppliers to answer questions, in general, or, in specific, about the Medicare program.

Response: We agree. We are adding language to new § 424.57(c)(4) limiting what questions must be answered to those pertinent to the use of the item at issue. Suppliers will also be requested to refer beneficiaries with Medicare questions to the appropriate regional carrier beneficiary toll-free line.

Maintains and Repairs Rental Items

Comment: One commenter requested that language be added to make clear that a supplier may meet that requirement through a service contract with another company.

Response: We agree that service contracts are acceptable. We make this clear in new § 424.57(c)(5).

Comment: Two commenters asked that we include a standard which would require suppliers to disclose patients' rights information.

Response: We agree and have added a new § 424.57(c)(7). Suppliers will be required to supply to each Medicare beneficiary with whom it does business a copy of the supplier standards it must meet in order to enroll as a Medicare Part B supplier. The handout will include the telephone number of the regional carrier for the area and will invite beneficiaries to call if they feel that their suppliers are not complying with the standards.

Comment: Another commenter asked what arrangements should be made for items which beneficiaries take with them when they travel.

Response: A supplier remains responsible for repairs even when a beneficiary is traveling. We suggest that suppliers inform their customers what procedures should be followed in emergency situations.

Comment: Another commenter asked that suppliers of prosthetics and orthotics be exempted from this standard.

Response: If items are not rented, the standard is inapplicable.

Returns of Substandard and Unsuitable Items

Comment: One commenter was concerned that orthotic and prosthetic devices could be considered substandard when compared with another device of "higher quality" or with more elaborate features and that when a beneficiary's condition changes, custom devices may no longer be "suitable." Similar comments were received from commenters representing durable medical equipment suppliers.

Response: It is not intended that "substandard" or "unsuitable" include the situations mentioned by the commenter. "Substandard" means less than full quality for the particular item, not as that item is compared to other types of items. An example would be an item which is unusable for the purpose for which it was purchased. "Unsuitable" means not appropriate for the beneficiary at the time it was fitted and/or sold.

Comment: Another commenter stated that suppliers should be required to accept as returns only those items that are in compliance with company policy on packaging integrity and/or local health laws, since some items cannot be resold.

Response: We do not agree that suppliers should not be obliged to accept opened packages of sterile products, if those packages contain defective parts or items or are not what was ordered by the physician for the beneficiary or what the beneficiary thought he/she was purchasing. Suppliers should not be reselling defective items. To avoid selling unsuitable items and, especially, if there is a question about what has been ordered for the beneficiary, the supplier should contact the beneficiary's physician for clarification.

Other Standards

Comment: Several Commenters suggested additional standards: maintenance of a physical facility and personnel; proof of product/professional liability insurance; proof of meeting basic business, health and safety standards; proof of meeting more rigorous standards for ostomy and PEN suppliers; successful completion of an on-site inspection; documentation of a quality assessment and improvement plan; and an equipment management plan and documentation of management, administration, and governing body.

Response: We agree that every supplier should have a physical facility and personnel. Since both a street address and an employer identification number or Social Security number will be required for every supplier on the disclosure of ownership form, we do not believe that it is also necessary to make physical facility and personnel a standard.

We do not believe it is necessary to require proof of liability insurance. We do not wish to interfere in the way suppliers conduct their business any more than is absolutely necessary. We also feel that such a provision might prevent some small, local suppliers from providing DMEPOS to Medicare beneficiaries.

The disclosure of ownership from also requires the number of any license the supplier holds and the name of the licensing body. Since every State and locality has different licensing requirements, we cannot monitor that all of these are met in every case. We would expect the appropriate licensing bodies to monitor compliance with their own requirements.

We do not intend to require stricter standards for some types of suppliers than other suppliers. We have seen nothing to justify that the business operations of some types of suppliers are more problematic than others.

Routine on-site inspections would be extremely expensive. We do not believe they would be relevant to the types of business standards in this regulation.

We do not agree that a supplier quality assessment plan is relevant and should be required, nor do we agree that an equipment management plan is necessary. We believe that acceptance/rejection of such plans would be undue interference in the way suppliers do business.

Documentation about individuals involved in management, administration and governing of the supplier is already required on the disclosure of ownership form. Since failure to disclose ownership information has the same effect as failure to meet supplier standards, we are, as a matter of organization, making disclosure of ownership a supplier standard.

Complaint Log

Comment: Some commenters were concerned that a few clerical errors in a log might be cause for suspension. Two commenters felt that the requirement for a complaint log was reasonable. Most commenters expressed concern that the complaint log requirement was too expensive, especially if oral complaints had to be documented, would not be useful and was duplicative of existing complaint resolution processes, such as those for pharmacists. Several commenters thought that a viable alternative would be a protocol for receiving and maintaining complaints and to demonstrate actions taken to resolve or respond to the complaint.

Response: First, we would note that the requirement to maintain a complaint log is not a supplier standard, and, thus, a failure to maintain it would not, in the absence of violation of one or more supplier standards, be cause for revocation of a supplier number. Failure to maintain a complaint log is merely evidence that a supplier standard may not have been met.

We agree that the requirement for a complaint log, as presented in the proposed regulation at § 424.55(g) (now new § 424.57(f)), was more onerous and burdensome than is necessary. Instead, we require in § 424.57(f) that suppliers must have documentable complaint resolution processes and maintain a separate file of all written complaints, related correspondence, and notes of action taken in response to oral or written complaints. We reserve the right for a carrier to, on its own initiative or at the direction of HCFA, require that a full complaint log be kept by any supplier for which there has been one or more beneficiary complaints (depending on the gravity of those complaints) which a carrier has had to help resolve about the supplier's failure to meet supplier standards or comply with the law. Limiting required documentation to complaint protocols and recordkeeping of materials produced in the normal course of supplier operations should eliminate most of the paperwork burden from most suppliers, focusing more intensive requirements on suppliers with a history of possible abuse. In all cases, however, suppliers will bear the burden of proof when a carrier follows up on complaints. Records of notes and other documentation may be useful in demonstrating: (1) A supplier's efforts to resolve such complaints; and (2) the effectiveness of its complaint protocol. Among the factors that a carrier may employ in evaluating a supplier's performance will be the gravity of the

complaint(s) and the overall effectiveness of the complaint protocol and its implementation. We welcome any comments on the efficacy of this revised requirement: (1) focusing burden on the appropriate suppliers; and (2) improving supplier complaint protocols over time.

Comment: Several commenters wanted to know what constitutes a complaint. One commenter recommended that the regional carriers disclose to the suppliers, upon request, any complaints received and validated by the carrier, with enough detail so that suppliers can take corrective action.

Response: A complaint is an allegation that a supplier is not fully complying with a regional carrier requirement, a standard, regulation or law. Normally, when a complaint is received by a carrier, the carrier works with the supplier and beneficiary to resolve the complaint. If, however, the complaint is part of a larger pattern of abuse which is being reviewed, or the supplier is under investigation for fraud, the beneficiary is usually advised that his/her complaint will be handled as part of the larger review or investigation. In these situations, it could be inappropriate to inform a supplier about the existence of a complaint.

Appeals Process

Comment: Many of the commenters were concerned about the lack of due process afforded those entities which are denied supplier numbers or which have their supplier numbers revoked. Notice and fair hearing, with a chance to submit evidence, were requested. One commenter suggested that no revocation should be imposed until after all administrative appeals had been exhausted, or at least, until a supplier has had time to respond to a notice of revocation. Another commenter suggested that suspension of payment was sufficient punishment.

Response: We agree that there should be a timely appeals mechanism for the decision to not grant or to revoke a supplier number. However, we do not view either action as a punishment. As explained above, we are instituting a system where only entities which meet certain standards can be issued a billing number. If those standards are not met, the entity no longer qualifies as a supplier for Medicare payment purposes. We believe this to be an administrative determination rather than a sanction, to be effective as of 15 days after a notice that the entity no longer qualifies as a supplier is sent by the carrier to the supplier.

As a result of these comments, we are adding a new § 405.874, Appeals of carrier decisions that supplier standards are not met. We specify in this section that the carrier must send notice of its determination by certified letter. The determination will be effective 15 days after the notice is sent by the National Supplier Clearinghouse, that is, claims for items or services furnished to beneficiaries on the 15th day after the notice, and later, will not be allowed. We will, therefore, require that the carrier make arrangements for the entity to have a fair hearing, before a carrier official uninvolved with the original determination, within one week after the notice is sent, or later, if at the request of the entity. A decision based on information presented by both the carrier and entity will be issued no later than two weeks after the hearing is held and will be sent by certified mail to the supplier. The entity or carrier may then appeal that decision, if unfavorable, to the Health Care Financing Administration (HCFA). A HCFA official will decide the appeal based on the information submitted by the carrier hearing officer within two weeks of receipt of the entity's or carrier's appeal, unless the HCFA official feels the information provided is incomplete. HCFA may request additional written information from either the carrier or entity. A decision will be issued within two weeks of when the last information is received by the official, or four weeks from when it was requested, whichever is earlier. The decision will be sent by certified mail to both the carrier and entity. Until all administrative appeals are exhausted, any claims submitted by the entity for the period the National Supplier Clearinghouse has determined the entity does not qualify as a supplier will be logged in and held by the carrier, but not processed.

The National Supplier Clearinghouse may reinstate a "supplier" if the entity completes a corrective action plan which rectifies its past violations of supplier standards and provides sufficient assurance of its intent to comply fully with the supplier standard in the future.

Coverage Policy

Comment: Many commenters favored establishing national standard coverage policy. A number of commenters focused on the fact that some beneficiaries, in the absence of point of sale jurisdiction, will no longer have Medicare coverage for some few items and, in other situations, will not be able to have Medicare reimburse them or their supplier for as many supply items per month. They point out that all Medicare beneficiaries pay the same premium, but since coverage and utilization are different around the country, those Medicare beneficiaries receive different benefits.

Response: While it is theoretically possible to issue a national coverage decision for each DMEPOS item, the process would be extremely long and labor intensive for HHS. We generally follow the process as forth in proposed rules published in the Federal Register on January 30, 1989. There are potentially thousands of items that could be subject to the process, many of which have a low volume of utilization and minimal, if any, variation in existing local coverage policy. It could take years to implement national coverage policy just for items represented by the top 100 most used or abused billing codes.

Carriers will continue to be able to formulate local medical review policy for any item in the absence of, or as an adjunct to, national coverage policy and apply that local medical review policy in their processing areas as described in section 7531 of the Medicare Carriers Manual, under the authority of section 1842 of the Social Security Act. Each of the four carriers must send any proposed changes in local medical review policy to HCFA (to assure there is no conflict with national policy) and to the professional associations representing suppliers, physicians, hospital discharge planners, etc., in its are a for comment. After the 45 day comment period, the carrier must evaluate each comment and then publish its final local medical review policy for the entire supplier population it serves. The local medical review policy change will be effective 30 days after publication.

Comment: One commenter stated that if we standardized coverage guidelines, we would not need to change from "point of sale" claims jurisdiction to "beneficiary residence."

Response: As discussed above, development of standardized national coverage policy for all items would be a lengthy and cumbersome undertaking. Changing to four regional carriers will mean a change to only four sets of medical review policy, except for those items to which a national coverage decision applies. We intend to require each regional carrier to formulate local medical review policy for at least the top 100 used/abused codes before it begins reviewing claims. The medical directors for the four carriers will be conferring on these policies and it is our belief that in most cases the resulting decisions will be similar, if not the same.

Utilization parameters will also be established at each of the four carriers. We also believe that the parameters will be very similar at all four carriers.

Comment: A number of commenters pointed out that coverage and utilization were standardized nationally for the parenteral and enteral nutrients (PEN) program, and that there was supplier satisfaction with that standardization.

Response: There are only a few items covered under the PEN program. It was relatively easy to establish national policy for those few items.

Comment: Some commenters were worried about the effect on beneficiaries of changes in coverage and utilization rules.

Response: For some beneficiaries, changes in medical review policy and utilization will mean fewer supply items per month or noncoverage of a rental item which another carrier had previously determined was covered. For these beneficiaries, the regional carriers will consider, on a case by case basis, whether some sort of temporary "grandfathering" ought to be employed, i.e., whether the rules under which the claim was originally processed should be continued with respect to that item and that beneficiary.

Payment Policy

Comment: Similar comments were received on our plan to determine payment rates for each State within each region. Most commenters believed that national payment rates should be established. One commenter believed that HCFA could, based on the lowest charge level authority in section 1842(b)(3) of the Act, for items paid both on the basis of reasonable charges and fee schedules, establish one national locality for reasonable charge and fee schedule purposes or regions for the orthotics and prosthetics fee schedule which coincide with the four regional carrier areas.

Response: We do not believe that HCFA has the authority to establish national pricing under either the durable medical equipment or prosthetic and orthotic fee schedules or for items for which reasonable charges are determined. The fee schedule for durable medical equipment consistently refers to "local" rates. We do not believe that national rates could be determined to be "local." The fee schedule for prosthetics and orthotics explicitly refers to local and regional rates. HCFA does have some latitude in determining those regional areas. The lowest charge level provision applies to the "reasonable charges" payment system, but not to the fee schedule system.

Comment: One commenter suggested that the regions of the carriers might be constrained to be those of the regional pricing areas. Other commenters believed that it would not be administratively difficult to maintain multiple fee schedules, since they have traditionally maintained multiple pricing locality information, but wanted to know how pricing would be determined in States where there is more than one carrier.

Response: Reasonable charge legislation, in section 1842 of the Act, also refers to "locality" as does the lowest charge level provision. Except for the pricing of parenteral and enteral nutrients, equipment and supplies, HCFA has historically defined "local area" or "locality" as being no larger than a State. Carriers processing claims for more than one State maintain separate pricing data for each State. For DME, prosthetics and orthotics, although most localities are currently Statewide, some States contain more than one locality, and in two areas, a locality includes areas in more than one State, since fee schedule localities are carrier-wide. In addition, for items paid on a reasonable charge basis, there may be multiple localities within a State.

We are proposing that each State area now be treated as a locality by the regional carriers for DMEPOS items. For States where there is currently more than one locality, fee schedule data will be combined by HCFA and projected for the 1993 billing year. For the first part of 1993, before the local carriers transfer their DMEPOS claims to the regional carriers, all of the local carriers in such States will pay DMEPOS claims under the new consolidated fee schedule amounts.

Similarly, for areas covering more than one State, i.e., the District of Columbia area which includes two counties in Maryland and two counties and one municipality in Virginia, and the Kansas City, Missouri, area which contains two counties in Kansas, pricing will be calculated for each by geographic area and that data will be combined with those for the rest of the State.

In addition, by January 1993, each State will have only one locality for all DMEPOS items paid under reasonable charge rules. Prevailing and customary charge data will be combined and/or divided for the January 1, 1993 update, where appropriate, so that the regional carriers will merely carry over the rates paid by the local carriers when they assume the workload.

Comment: Another commenter asked how we would handle payment for some rentals for which the payment rates will change during the 15 month rental period.

Response: Some beneficiaries will be phased into new pricing or local medical review policy. The regional carriers will make those decisions on a case-by-case basis.

Part B Claims Processed By Part A Intermediaries

Comment: One commenter asked HCFA to be more specific about what claims would be transferred from Part A intermediaries. The effect on billings for ambulatory surgical centers, etc., was also questioned.

Response: We are planning to transfer most Part B claims for DMEPOS items from the fiscal intermediaries to the regional carriers approximately one year after the phase-in of DMEPOS claims from local carriers has been accomplished.

These claims will not include claims for any items for which payment is bundled into a larger payment package, such as for a hospital inpatient stay or an encounter in a hospital outpatient department, or claims for items which are supplied "incident to" services in a physician's office (see 42 CFR 410.26) or "incident to" a physician's service in a rural health clinic (see 42 CFR 405.2413).

Comment: The same commenter questioned HCFA's authority to transfer such claims, particularly claims submitted by home health agencies. It was also suggested that there would need to be a specific change in the regulations to permit transfer of such claims.

Response: Carriers have the primary responsibility to determine reasonable charges and fee schedule amounts for part B items. There is no prohibition, except for claims submitted by home health agencies, to requiring that they be processed by the regional carriers. We believe that DMEPOS claims would be more efficiently processed by the regional carriers which will maintain the reasonable charge levels and fee schedules for the area in which a beneficiary resides. Each of those carriers will also have uniform coverage guidelines and utilization parameters for items furnished to beneficiaries residing within it region, which an intermediary would find difficult to apply. Since there will be no difference in payment rates, we do not believe that another regulation will be necessary to transfer these claims. Intermediaries will continue to process claims for which payment is made on a reasonable cost basis or under the prospective payment system and claims for items provided by home health agencies.

Common Working File

Comment: Several recommendations were made by commenters that suppliers be allowed to directly access the Common Working File (CWF) to verify permanent address, utilization history, eligibility and Medicare Secondary Payer status.

Response: We do not believe that supplier access to the CWF is necessary. As explained above, the primary source of information on a beneficary's permanent residence is the beneficiary. The beneficiary should also be the primary source of information on eligibility, utilization history, Medicare secondary payer (MSP), etc. If a beneficiary is not competent to supply this information, the guardian, custodian or representative payee of the beneficiary will be the best source of information.

Comment: One commenter requested that each regional carrier be given extracts of all DMEPOS claims transactions contained in CWF and that the CWF file be enhanced to include information on other claims which will have an impact on the review and payment of DMEPOS claims.

Response: We do not believe it is necessary for each regional carrier to have access to all CWF host sites. The regional carriers will be linked to each CWF host site in their DMEPOS regions and the host for Railroad Retirement beneficiary claims. Claims for beneficiaries whose records are located at other CWF host sites outside the DMEPOS region will be sent electronically to the appropriate CWF host. This is considered out of service area processing. For most out of service area claims this should mean only a two or three day turn around process.

We do have plans to enhance the CWF so that the processing of DMEPOS claims can be facilitated, particularly during the transition period. A separate DMEPOS claim record, Certificate of Medical Necessity (CMN) transaction record, a CMN auxiliary file and some unique dispositions and trailers are being developed for DMEPOS processing.

These data will be stored so that a duplicate claim check can be run against other DMPEOS claims.

The CMN record will collect beneficiary and item specific information on medical necessity, e.g., that a Certificate of Medical Necessity for oxygen has been received and accepted and is valid through a certain date or that a physician's prescription has been received and accepted for a supply item.

Electronic Media Claims

Comment: While there was support for more intensive electronic media claim (EMC) processing, two commenters indicated that suppliers need assistance in implementing EMC; one that financial incentives would be necessary: $1 per claim for the first year of EMC submission. On the other hand, some commenters suggested that it would be helpful to provide free software to suppliers, that current non-national format claims ought to be allowed to be submitted for an interim period and that all current EMC "grandfathering" arrangements will need to be rescinded.

Response: We plan to encourage all suppliers to adopt EMC submissions of claims and medical documentation. Suppliers with special billing problems will be given special assistance. While we do not, believe that financial incentives, per se, would be appropriate, we would not discourage a carrier from proposing in its bid to become a regional carrier that it would provide free DMEPOS-specific software to all suppliers.

We do not believe that we can compromise on our requirement that the national standard format be used for submission of EMC claims. The new regional carriers will be adjusting to too many other changes. We will not further complicate transition by requiring the regional carriers to support multiple EMC formats. We expect that regional carriers will test claims submissions from suppliers several months before claims are actually received for processing. This should allow sufficient time to "debug" for all suppliers wishing to use EMC. In addition, suppliers may voluntarily choose to begin submitting EMC claims to their current carriers under the national standard format at an earlier date to mitigate conversion problems when the regional carriers assume the workload.

Payment Adjustments

Comment: One comment suggested that since small suppliers had been disadvantaged by "point of sale" jurisdiction rules, they should receive retroactive payment adjustments to make them whole.

Response: We disagree. We do not think it would be appropriate to change retroactively jurisdiction rules or the effects of those rules. We also believe that we do not have the legal authority to make such retroactive adjustments.

Ambulance Claims

Comment: One commenter was concerned that this regulation would change rules affecting when Unique Physician Identification Numbers (UPINs) would be required for referring physicians on ambulance claims.

Response: This regulation has no effect on when UPINs are required on ambulance claims. The only effect of this rule on ambulance suppliers is the requirement for them to submit ownership and control information at the request of their carriers.

Independent Physiological Laboratory Claims

Comment: One commenter objected to a change in claims jurisdiction policy for independent physiological laboratory claims.

Response: This regulation does not affect claims jurisdiction for independent physiological laboratory claims. Disclosure of ownership and control rules do apply to independent physiological laboratories.

Technical Corrections

In addition to the revisions discussed above, we are making technical corrections to §§ 405.505, 421.200 and 421.210. In § 405.505, Determination of locality, we revise the definition of "locality" to specify that a locality is the geographical area for which the carrier is to derive the reasonable charges or fee schedule amounts for services or items, to include a State or larger area as a locality. We are making this revision so that it will conform with § 421.210(e) which requires that the regional carriers pay on a State-wide locality basis.

We are making a technical correction to § 421.200 Carrier function, to clarify that a regional DMEPOS carrier is exempt from the requirements in that provision.

In § 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies, we are adding new paragraph (a)(7) which will allow HCFA to assign the processing of other Part B items to the regional carriers, when coverage for those items is established or items normally provided by physicians, such as pneumococcal and hepatitis B vaccines, are self-administered. Though suppliers and physicians will be notified when new coverage is established, it should be assumed that all items not bundled into a physician or facility payment should be billed to a regional DMEPOS carrier.

In new § 424.57, Special payment rules for items provided by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers, we add a definition of the acronym "DMEPOS",

and a definition of "supplier" for the purpose of this provision to specify that a supplier is an entity or individual, including a physician or Part A provider, which sells or rents Part B covered items to Medicare beneficiaries under the standards of § 424.57(c), and an enrolled supplier is a supplier which has an active billing number. We had previously proposed to add this information to § 424.55, but, for purposes of clarify, have decided to create a new provision applicable only to DMEPOS suppliers.

Effective Dates

The regulation provisions are effective August 17, 1992. The disclosure of ownership and supplier standards provisions will be applied to new suppliers August 17, 1992 and for all other suppliers on January 1, 1993. The change to beneficiary residence claims jurisdiction will be implemented for claims submitted to regional carriers beginning July 1, 1993.

IV. Criteria and Standards for Evaluating Regional Carriers

Section 1842(b)(2) of the Act requires the Secretary to publish in the **Federal Register** criteria and standards for the efficient and effective performance of contract obligations, and provide an opportunity for public comment prior to implementation.

We proposed to designate four regional DMEPOS carriers. The proposed designation using current data on claims volumes and beneficiary distribution would result in four approximately equal workload areas. These carriers would process electronically submitted claims in one standard national electronic media format. We would expect that these carriers would have exclusive authority over all DMEPOS claims currently paid for by part B local and specialty carriers, and will be given jurisdiction over those part B DMEPOS claims processed by fiscal intermediaries, except for items furnished by home health agencies. The four regional DMEPOS carriers would take over the responsibilities of the two current regional carriers processing claims for enteral and parenteral nutrients, supplies, equipment and immunosuppressive drugs.

Under section 1842(b)(2) of the Act, we are required to develop criteria, standards, and procedures to evaluate a carrier's performance of its function under its contract with us. We publish the criteria and standards in the **Federal Register** in order to allow the public an opportunity to comment on them before they are implemented. This preamble announces the criteria and standards to be used to measure the effectiveness and efficiency of the regional DMEPOS carriers.

In the event that the DMEPOS regional carrier contract is awarded to an organization which also has a contract with HCFA to perform the services of a Medicare carrier, the effectiveness and efficiency of that Medicare carrier contract will be evaluated with the criteria and standards applicable to all Medicare carriers. However, the organization's performance under the DMEPOS regional carrier contract will be evaluated using the criteria and standards applicable to DMEPOS regional carriers.

A. Criteria and Standards—General

We are establishing six separate criteria for evaluating regional DMEPOS carriers. Within each criterion we have identified the performance standard which, when measured, will evidence how well each DMEPOS regional carrier is performing.

The initial evaluation period for DMEPOS regional carriers will be from October 1, 1993 through September 30, 1994. We intend for subsequent evaluation periods to also follow the Federal fiscal year, October 1 through September 30.

The criteria and standards can be used to measure carrier performance at any time during the evaluation period and measurements can occur more than one time during a evaluation period. If a carrier's performance in a standard is measured two or more times during the evaluation period, all evaluations will be done on a cumulative basis back to the beginning of the evaluation period. Should a carrier's performance be deficient as measured against the criteria and standards at any time during the evaluation period, contract action may be initiated.

The criteria and standards will be contained in the contract with the regional DMEPOS carrier and will be effective for the duration of the contract, subject to revision if the contract is renegotiated or new contracts are awarded. We will publish in the **Federal Register** any revisions to the criteria and standards. Existing criteria and standards will remain in effect until the first day of the first month after the revisions are published in the **Federal Register**.

It is not our intention to revise either the evaluation period or the standards and criteria which will be used during the evaluation period once this information has been published in the **Federal Register**. However, on occasion, either because of administrative mandate or Congressional action, there may be a need for changes which have direct impact upon the criteria and standards previously published, or which require the addition of new criteria and standards, or which cause the deletion of previously published criteria and standards. Should such changes be necessitated, we will issue a **Federal Register** notice prior to implementation of the changes. The criteria and standards may also be revised to reflect changes in performance expectations. Should this become necessary, we will negotiate these changes to the standards with the regional DMEPOS carriers and we will publish changes in the **Federal Register** prior to implementation. Changes in standards and criteria will not be effective any earlier than the first day of the first month following publication.

As necessary, instructional issuances for implementing the criteria and standards will be published to ensure that the criteria and standards are implemented uniformly and accurately.

The **Federal Register** notice will be republished and the effective date revised if changes are warranted as a result of the public comments received on the standards and criteria.

B. Action Based on Performance Evaluations

We may initiate action based on these performance criteria and standards. We plan to consider the results of the evaluation in our determinations on entering into, renewing/extending, or terminating contracts or contract amendments with regional DMEPOS carriers. Such decisions are made on a case-by-case basis and depend primarily on the nature and degree of performance. More specifically, they depend on:

1. Relative performance compared to other regional DMEPOS carriers;
2. Number of standards in which acceptable or deficient performance occurs;
3. Extent of each deficiency; and
4. Relative significance of the standards for which acceptable or deficient performance occurs within the overall regional DMEPOS carrier criteria and standards.

Decisions on contract actions are made after considering these factors in terms of their relative significance and impact on the effective and efficient administration of the Medicare Program.

C. Scoring System

For a regional DMEPOS carrier to satisfactorily meet the overall criteria

and standards, the carrier must meet the performance requirements for each and every standard.

In general, if a carrier meets the level of performance required by its contract, it will pass each standard. Any rating below basic contractual performance obligations constitutes a deficiency whereby appropriate contract action may be initiated (see section B above). The carrier may be required to develop and implement a corrective action plan when performance problems are identified. The carrier will be monitored to assure effective and efficient compliance with the corrective action plan and improved performance where standards are not met.

D. Criteria and Standards for Regional DMEPOS Carriers

We will use six criteria to evaluate the overall performance of regional DMEPOS carriers. They are: (1) Quality; (2) efficiency; (3) service; (4) fraud and abuse; (5) National Supplier Clearinghouse; and (6) Statistical Analysis Regional DMEPOS carrier.

The six criteria contain a total of 12 standards. There are two for quality, four for efficiency, three for service, one for fraud and abuse, one for National Supplier Clearinghouse, and one for Statistical Analysis Regional DMEPOS carrier.

1. Quality Criterion

A DMEPOS regional carrier must pay claims accurately and in accordance with program instructions. The regional DMEPOS carrier is required to:

Standard 1. Process claims at an accuracy rate of 98.5%.

Claims are processed accurately with respect to coverage determinations, secondary payer consideration, supplier enrollment and the correct amount is approved for payment.

Standard 2. Implement measures to improve program effectiveness.

The regional DMEPOS carriers are expected to undertake actions to promote effective program administration with respect to DMEPOS claims. Such activities may include: overpayment recovery and offsetting of claim payment; assuring the proper submission of certificates of medical need; review of the implementation of medical fee schedules and reasonable charge updates, medical review activities; and implementation of coverage policy.

2. Efficiency Criterion

The regional DMEPOS carrier is required to:

Standard 1. Process 95.0% of clean claims within mandated timeframes and process 97.0% of all claims within 60 days.

Standard 2. Ensure that the Electronic Media Claims (EMC) goal is achieved.

DMEPOS regional carriers are advised of their specific goal for EMC prior to the evaluation period. In determining a carrier's specific goal, HCFA considers such factors as the extent to which DMEPOS claims have historically been submitted in EMC format.

Standard 3. Ensure that total actual expenditures are at or below budget authority and administrative funds are drawn in line with monthly expenditures.

Evaluates performance in controlling expenditures in line with the Notice of Budget Approval.

Standard 4. Ensure that unit cost does not exceed maximum negotiated unit cost.

Evaluates performance in controlling unit cost so that it is within the maximum negotiated unit cost.

3. Service Criterion

Beneficiaries and suppliers are served by prompt and accurate administration of the program in accordance with all applicable laws, regulations and general instructions. The regional DMEPOS carrier is required to:

Standard 1. Ensure that 95.0% of reviews and hearings are accurate and timely.

Reviews and hearings are evaluated to determine that decisions are accurate and communicated to the appropriate party within 45 days for reviews and 120 days for hearings.

Standard 2. Ensure that 95.0% of inquiries are responded to timely and accurately.

Telephone calls are answered within 120 seconds, callers do not get a busy signal more than 20% of the time, and responses are accurate. Written responses are accurate and prepared within 30 calendar days of date of receipt.

Standard 3. Respond to beneficiary and supplier education and training needs.

Carriers are expected to undertake actions that serve the beneficiary and supplier communities by explaining program requirements through up-to-date information, periodic educational training and bulletins, publishing and updating a supplier manual, meeting with trade associations and coordinating with local contractors on DMEPOS issues.

4. Fraud and Abuse Criterion

The regional DMEPOS carrier is required to:

Standard 1. Conduct an effective Program Integrity Program.

The regional DMEPOS carriers will be evaluated on a number of activities including: effectiveness in identifying and developing cases of fraud and abuse, bringing the cases to conclusion and collecting inappropriate payments, promoting beneficiary education in referring questionable suppliers or practices, and searching out supplier practices which are inappropriate.

5. National Supplier Clearinghouse (NSC) Criterion

Standard 1. Properly Administer the NSC.

The NSC will be reviewed to ensure it meets its various requirements such as: processing new and renewal applications for billing numbers, maintaining supplier file, matching OIG sanctioned suppliers, and enforcing supplier standards. In addition, the NSC will be evaluated based upon its performance in conducting statistical analysis of data to identify potential areas of over utilization, overpayments, fraudulent or abusive claims practices and other areas of concern to be identified by HCFA.

6. Statistical Analysis Regional DMEPOS Carrier Criterion

(The Statistical Analysis DMEPOS carrier function will be assigned to one of the Regional DMEPOS carriers. It will perform the functions measured by the standard.)

Standard 1. Properly Administer the Statistical Analysis Regional DMEPOS carrier program.

The Statistical Analysis Regional DMEPOS Carrier will be reviewed to ensure it meets its various requirements such as: analyzing national reports to identify trends, aberrancies, and utilization patterns, generating reports according to HCFA specifications, serving as the HCPCS definition resource center, developing national PEN pricing and national floors and ceiling for DME prices.

V. Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish an initial regulatory impact analysis for any final rule that meets one of the Executive Order criteria for a "major rule"; that is, would be likely to result in—

An annual effect on the economy of $100 million or more;

A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of the United States based enterprises to compete with Foreign-based enterprises in domestic or export markets.

In addition, we generally prepare an initial regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we do not consider carriers as small entities. Therefore, a RFA will not be required.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any regulation that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds. Unless claims for DMEPOS submitted by hospitals are moved to regional carriers, there will be no impact on hospitals. At this time, there are no definite plans to move these claims.

In light of the fact that many suppliers are in favor of these rule changes and for the reasons we have determined below, we do not believe that the threshold criteria under E.O. 12291 and RFA will be met. However, in the spirit of E.O. 12291 and the RFA, we are voluntarily providing the following information.

The contracts for the 4 regional DMEPOS carriers will be obtained competitively. Rather than merely select among existing Medicare carriers, as the Act permits, all entities which qualify as a "carrier" under the Act may bid for the contracts. We believe that this competition will allow the procurement of regional carriers which are both the most effective and the most efficient in DMEPOS processing.

DMEPOS claims compose only 5 percent of local Medicare carrier workloads. Regional carriers will be able to focus their attention on just DMEPOS claims. The staff will become expert in the processing of these claims. Special computer processing has been designed for these claims. We believe that his increased focus and expertise will result in significant program savings:

- Medical necessity criteria are being developed for all high volume and high cost items. Based on these criteria, claims will be evaluated by DMEPOS specialists. The closer scrutiny based on well defined standards should result in the denial of claims for items which are not medically necessary or the reduction of payment for items that are more complex than are medically necessary. Many such items have not been subjected to such comprehensive review, because there was no emphasis on developing the necessary review criteria.
- There should also be some savings achieved by eliminating the ability of suppliers to bill carriers with higher reimbursement, lenient local medical review policy and/or more generous utilization parameters. While some suppliers are being paid less now than they will under "beneficiary residence" claims jurisdiction, more suppliers are maximizing their profits by billing carriers which would pay more than the carrier local to the beneficiary to whom they sold a DMEPOS item.
- There will be additional savings attributable to both the prevention of fraud and the more effective and timely identification of fraud. Increased vigilance over all aspects of the DMEPOS program should prevent many suppliers from submitting fraudulent claims. The emphasis on beneficiary education, especially detection of potentially fraudulent practices, should also deter fraud.
- The new carriers will expand use of prepayment computer editing and cross checking to detect many fraudulent claims. The regional carriers will be assisted in their postpayment review by the SADMERC which will perform sampling and analysis of a national database of DMEPOS claims histories. Suppliers will find it more difficult to obscure fraudulent billing because of the more focused national postpayment review. Finally, each regional carrier will have a dedicated fraud unit which will be devoted to developing fraud cases for further investigation and prosecution.

We anticipate transitional questions from physicians who prescribe, and hospital discharge planners who help patients to obtain, DMEPOS. Educational campaigns will be conducted for these groups. There will also be an aggressive education campaign directed to both small and large suppliers, both about the changes in the program, and the desirability of submitting bills via electronic media claims (EMC) or in formats compatible for optical character readers.

We also anticipate questions from beneficiaries. An educational campaign is being designed to describe for them the change to regional carriers and to emphasize their role in the successful control of fraud and abuse in the DMEPOS industry. Since suppliers will no longer be able to choose the carrier to which they submit their bills, and thus, the payment rate they will receive, some beneficiaries will pay higher or lower copayment amounts. Those whose bills had been submitted to carriers with relatively high payments for supplier items may be subject to smaller copayments and a few beneficiaries, whose claims will now be priced at higher rates, will experience larger copayments. However, in many cases, these copayments will be paid for by Medicaid or a Medigap insurer. For some items, non-participating suppliers may no longer accept assignment, which may increase balance billing. In addition, the new supplier standards, including recordkeeping and disclosure requirements, may discourage some small suppliers from serving Medicare beneficiaries, thereby, limiting some beneficiaries living in small towns or rural areas to suppliers which market by catalog.

Most small suppliers which now bill a local carrier with which they are familiar would have to bill an unfamiliar carrier. On the other hand, large suppliers which now have set up their businesses so that they may bill only one carrier, may have to bill up to four carriers. Large suppliers which bill many local carriers may have the number of carriers which they bill reduced from as many as 34 to four.

All suppliers will be paid the same amounts for similar products used by beneficiaries residing within the same State. Their claims would also be subject to similar local medical review policies. HCFA would no longer be giving an unfair competitive advantage to larger suppliers which, under the current "point of sale" system, structure their businesses so that the "point of sale" is located within the area of a carrier with favorable documentation rules, utilization screens, local medical review policy or pricing for their products.

Suppliers currently filing EMC that are not currently using the standard EMC format to bill their local carriers would have to adapt their billing formats to HCFA's national standard format. This may cause a temporary reduction in the total number of DMEPOS claims to be processed by EMC. Since some suppliers may be unwilling or unable to establish completely new billing systems before the regional carriers begin processing every effort will be made to assist these suppliers in converting to the national

standard format while still being served by their local carriers. For those suppliers unable to convert to the national standard format before the claims are transferred to the regional carriers for processing, it will be expected that they will submit EMC claims before the end of the first processing year under the regional carriers. We expect, however, that, with aggressive EMC marketing and the reduced number of carriers, more suppliers will choose to utilize EMC. Suppliers using the national standard format at their local carriers would be able to bill their regional carriers electronically, immediately upon transition to the regional carriers.

Since all suppliers will need to apply for a billing number at the new carriers, we have developed a standard form, the HCFA–192. Suppliers will be required to submit, as part of their request for a billing number, certification that they meet supplier standards and information on those individuals with ownership and control interests or who are managing employees, and further identify any that have had any penalties, assessments or exclusions against them or against other suppliers with which they have been, or are, associated. Billing numbers must be renewed every 3 years.

The improved control of supplier billing numbers and change to beneficiary residence carrier jurisdiction should have positive impact on other third party payors, especially Medigap State agencies. We expect that the benefits of enforcing supplier standards will spill over into services and supplies reimbursed by other payors. Also, the consolidation of all claims for services and supplies provided to beneficiaries in a geographic area will enable the DMEPOS regional carriers to develop more comprehensive utilization profiles, facilitating the identification of fraudulent or abusive supplier billing practices. The recent General Accounting Office report, "Health Insurance: Vulnerable Payors Lose Billions to Fraud and Abuse" (May 19, 1992), suggested that one means of addressing the fraud and abuse in the health care industry would be better coordination among third party payors. We believe that proposed changes in the Medicare claims processing would promote the suggested coordination among insurers.

We expect all carriers, except any local carrier designated to act as a regional carrier, to experience a decrease of about 5 percent of their current claims workload. We expect that regional DMEPOS carriers would each process approximately 6 million claims. Increased start up costs for the first few years are expected. However, these costs would be partly offset by the reduced cost per claim resulting from economies of scale. There may be some administrative savings, both for the carriers losing DMEPOS claims, which must be handled quite differently from other claims, and for the regional carriers which will be handling an optimum number of claims for efficient processing. There will, however, be initial one time transition costs, for the first 1 to 2 years after implementation, as well as initial temporary increases in professional and beneficiary relations costs. While there will be some savings from increased use of EMC, these savings will primarily be achieved as the result of separate EMC initiatives. EMC claims for DMEPOS are currently processed at half the cost of hard copy claims. Some additional savings may be possible with increased use of optical character readable claims. With use of these techniques and suppliers preparing and submitting unassigned claims for beneficiaries (as required by section 1848(g)(4) of the Act, as enacted by section 6102 of Pub. L. 101–239), we expect fewer claims should be billed and processed in a hard copy format at a higher price.

Preliminary analysis suggests that the DMEPOS carrier criteria and standards will not result in significant utilization of Federal resources to administer them. We expect minimal effects on carrier costs due to this notice since the criteria and standards measure functional responsibilities that the carrier must be performing as a Medicare DMEPOS carrier.

The preamble to this rule sets forth the criteria and standards to be used for evaluation of Medicare regional DMEPOS carriers. This rule does not require specific performance of the operations being evaluated. It may have an effect on carrier operations such as bill processing, beneficiary services and provider services which could indirectly affect a substantial number of providers and suppliers.

The most important indirect effect on providers and suppliers as a result of this notice will be to ensure that they are paid timely and accurately. Therefore, we have determined, and the Secretary certifies that this rule does not meet the requirements to be determined a major rule nor does it meet criteria as having a significant impact on a substantial number of entities.

VI. Response to Public Comments

Because of the large number of items of correspondence we normally receive on a final rule with comment, we are unable to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date and time specified in the "COMMENT PERIOD" section of this preamble, and we will respond to comments in the preamble to the final rule.

VII. Collection of Information Requirements

Sections 420.206, 421.210 and 424.57(c)(7) and (f) of this final rule contain information collection requirements that are subject to the Office of Management and Budget review under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). The information collection requirements concern the information necessary to request a billing number and for disclosure of ownership and control and the identities of managing employees. The respondents who will provide the information will be the suppliers. Public reporting burden for this collection of information is estimated to be 160,000 hours. We estimate that 160,000 suppliers will complete the information which is estimated at one hour per supplier. A notice requesting comments on the HCFA–192 was published in the **Federal Register** on October 30, 1991. OMB approval was obtained December 31, 1991.

Section 424.57(f) of the final rule seeks to establish the maintenance of a beneficiary complaint log, an additional information collection requirement on suppliers about which a carrier has obtained one or more complaints which it has to help resolve. The information to be collected in that log would include the date and nature of a beneficiary's complaint about a supplier's perceived noncompliance with supplier standards, the identity of the complainant and the date and nature of the response to the complaint. If a complaint is not investigated by the supplier, then the reason for the lack of investigation should be noted along with the identity of the person making the decision not to investigate. Other suppliers will need only to have complaint resolution protocols and maintain a file of all written complaints and related correspondence and notes of actions taken in response to oral and written complaints. We estimate that 130,000 suppliers will each require one hour to develop and document complaint resolution protocols creating a one-time paperwork burden of 130,000 hours. We further estimate that 130,000 suppliers will each receive 15 complaints per year and that the documentation and recordkeeping of materials already

produced in the normal course of supplier operations will require no more than 5 minutes each for a recordkeeping burden of 162,500 hours. For those suppliers which are asked to develop and report to Medicare more extensive records, probably no more than 100 to 200 suppliers, we estimate a burden of 15 minutes for each of 15 complaints, for an additional burden of 375 to 750 hours. The total burden would be approximately 293,000 hours. These requirements have been submitted to OMB for review and will not be effective until OMB approval is received. Comments on these requirements should be forwarded to OMB.

Finally, we will require all suppliers to give a copy of the supplier standards to each Medicare beneficiary with whom they do business. The National Supplier Clearinghouse will supply a copy to each enrolled supplier which may be photocopied. We estimate the burden for each supplier to average about 20 minutes per year, including photocopying and handing out the standards, which is about 53,500 hours. A notice will be published in the **Federal Register** when approval is obtained.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 420

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicare.

42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR chapter IV is amended as follows:

A. Part 405 is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405, subpart E continues to read as follows:

Authority: Secs. 1102, 1814(b), 1832, 1833(a), 1834(b), 1842(b) and (h), 1861(b) and (v), 1862(a)(14), 1866(a), 1871, 1881, 1886, 1887, and 1889 of the Social Security Act as amended (42 U.S.C. 1302, 1395f(b), 1395k, 1395l(a), 1395m(b), 1395u(b) and (h), 1395x(b) and (v), 1395y(a)(14), 1395cc(a), 1395hh, 1395rr, 1395ww, 1395xx, and 1395zz).

2. In subpart E, § 405.505 is revised to read as follows:

§ 405.505 Determination of locality.

"Locality" is the geographical area for which the carrier is to derive the reasonable charges or fee schedule amounts for services or items. Usually, a locality may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical services areas (interstate or otherwise), comparable in concept to "trade areas." Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore shall delineate localities on the basis of their knowledge of local conditions. However, distinctions between localities are not to be so finely made that a locality includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

3. The authority citation for part 405, subpart H is revised to read as follows:

Authority: Secs. 1102, 1831–1843, and 1871 of the Social Security Act, as amended. (42 U.S.C. 1302, 1395j–1395v, and 1395hh.)

4. A new § 405.874 is added to subpart H to read as follows:

Subpart H—Review and Hearing Under the Supplementary Medical Insurance Program

* * * * *

§ 405.874 Appeals of carrier decisions that supplier standards are not met.

(a) An entity serving as a National Supplier Clearinghouse must act promptly to determine if any entity submitting a request for a billing number as a Medicare supplier of part B items meets the standards set forth in part 424. Effective July 1, 1993, the National Supplier Clearinghouse must accept, reject or request additional information within 15 days of the receipt of an enrollment application.

(b) If the National Supplier Clearinghouse disallows an entity's request for a billing number or revokes, with the concurrence of HCFA, an entity's billing number, the National Supplier Clearinghouse notifies the entity by certified mail. Revocation is effective 15 days after the National Supplier Clearinghouse mails notice of its determination. The carrier disallows payment for items furnished by the supplier beginning with that effective date. The notice must inform the entity of the reason for the rejection or revocation, its right to appeal, the date by which it must file that appeal (90 days after the postmark of the notice) and the address to which the appeal must be sent in writing.

(c) A fair hearing officer not involved in the original determination to disallow an entity's request for a billing number, or to revoke an entity's billing number, must schedule a hearing to be held within one week of receipt of an appeal, or later at the request of the entity. Both the entity and carrier may offer evidence. The hearing officer issues a notice of his/her decision within 2 weeks of the hearing. The notice is sent by certified letter to HCFA, the carrier, and the appealing entity. This notice must include information about the supplier's further right to appeal, the carrier's right to appeal, the date by which the appeal must be filed (90 days after the postmark of the notice) and the address to which the appeals must be sent in writing. Either the carrier or entity may appeal the hearings officer's decision to HCFA.

(d) A HCFA official, designated by the Administrator of HCFA, must make an appeal decision based on the evidence presented to the fair hearing officer and his or her decision. The HCFA official requests any additional information he or she deems necessary from either the carrier or the entity within two weeks of receipt by the HCFA of the appeal. Notice of the HCFA official's decision—

(1) Is issued within two weeks of when the last information is received is received by the HCFA official, or four weeks of when the information is requested, whichever is shorter, unless the party appealing the fair hearing decision requests a delay;

(2) Is sent by the HCFA official by certified mail to both the carrier and the entity; and

(3) Contains information on any further appeals the entity and carrier may have.

(e) A billing number is not issued, or remains revoked, and payment is not made, for items or services furnished by any entity which a carrier determines does not qualify for a billing number, until the carrier (upon reapplication of the entity), a fair hearing officer, or a HCFA official designated to hear such appeals, determines that the entity

qualifies for a billing number. Any claims for items or services furnished after revocation of the supplier's billing number and submitted by the entity during the appeals period are held and not processed, i.e., are neither approved, denied or developed, until all administrative appeals have been exhausted. If an entity is determined not to have qualified for a billing number in one period but to have qualified in another, the carrier pays for claims for items sold or rented to beneficiaries during the period the entity qualified as a supplier. If there is evidence of an overpayment, see subpart C of part 405 of this Chapter.

(f) A billing number may be reinstated after revocation when an entity completes a corrective action plan, to which HCFA has agreed, and provided sufficient assurance of its intent to comply fully with the supplier standards.

B. Part 420 is amended as follows:

PART 420—PROGRAM INTEGRITY: MEDICARE

1. The authority citation for part 420 is revised to read as follows:

Authority. Secs. 1102, 1124, 1124A, 1126, 1833(e), 1866 and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a–3, 1320a–5, 13951(e), 1395cc, and 1395hh).

2. The heading of subpart C is revised to read as follows:

Subpart C—Disclosure of Ownership and Control Information

3. Section 420.200 is revised to read as follows:

§ 420.200 Purpose.

This subpart implements sections 1124, 1124A, 1126, 1833(e), 1861, and 1866 of the Social Security Act. It sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and the identities of managing employees. It also sets forth requirements for disclosure of information about a provider's or Part B supplier's owners, those with a controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs.

4. In § 420.201, the definition of "Disclosing entity" is revised and the definition of "Supplier" is removed to read as follows:

§ 420.201 Definitions.

* * * * *

Disclosing entity means:

(1) A provider of services, an independent clinical laboratory, a renal disease facility, or health maintenance organization (as defined in section 1301(a) of the Public Health Service Act);

(2) A carrier or other agency or organization that is acting for one or more providers of services for purposes of part A and part B of Medicare; and

(3) A part B supplier, as defined in § 400.202 of this chapter.

* * * * *

5. Section 420.204 is revised to read as follows:

§ 420.204 Principals convicted of a program-related crime.

(a) *Information required.* Prior to HCFA's acceptance of a provider agreement or issuance or reissuance of a supplier billing number, or at any time upon written request by HCFA, the provider or part B supplier must furnish HCFA with the identify of any person who:

(1) Has an ownership or control interest in the provider or part B supplier;

(2) Is an agent or managing employee of the provider or part B supplier; or

(3) Is a person identified in paragraph (a)(1) or (a)(2) of this section and has been convicted of, or was an owner of, had a controlling interest in, or was a managing employee of a corporation that has been convicted of a criminal offense, subjected to any civil monetary penalty, or excluded from the programs for any activities related to involvement in the Medicare, Medicaid, title V or title XX social services program, since the inception of those programs.

(b) *Refusal to enter into or renew agreement or to issue or reissue billing numbers.* HCFA may refuse to enter into or renew an agreement with a provider of services, or to issue or reissue a billing number to a part B supplier, if any person who has an ownership or control interest in the provider or supplier, or who is an agent or managing employee, has been convicted of a criminal offense or subjected to any civil penalty or sanction related to the involvement of that person in Medicare, Medicaid, title V or title XX social services programs. In making this decision, HCFA considers the facts and circumstances of the specific case, including the nature and severity of the crime, penalty or sanction and the extent to which it adversely affected beneficiaries and the programs involved. HCFA also considers whether it has been given reasonable assurance that the person will not commit any further criminal or civil offense against the programs.

(c) *Notification of Inspector General.* HCFA promptly notifies the Inspector General of the Department of the receipt of any application or request for participation, certification, re-certification, or for a billing number that identifies any person described in paragraph (a)(3) of this section and the action taken on that application or request.

6. Section 420.205 is revised to read as follows:

§ 420.205 Disclosure by providers and part B suppliers of business transaction information.

A provider or part B supplier must submit to HCFA, within 35 days after the date of a written request, full and complete information on—

(a) The ownership of a subcontractor with which the provider or part B supplier has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000;

(b) Any significant business transactions between the provider or part B supplier and any wholly owned supplier or between the provider or part B supplier and any subcontractor, during the 5 year period ending on the date of the request;

(c) The names of managing employees of the subcontractors;

(d) The identity of any other entities to which payment may be made by Medicare, which a person with an ownership or control interest or a managing employee in the subcontractor has or has had an ownership or control interest in the 3-year period preceding disclosure; and

(e) Any penalties, assessments, or exclusions under sections 1128, 1128A and 1128B of the Act incurred by the subcontractor, its owners, managing employees or those with a controlling interest in the subcontract.

7. In § 420.206, paragraph (a) introductory text is republished, paragraphs (a)(1), (a)(3), (b)(2), (b)(3), and (c) are revised to read as follows:

§ 420.206 Disclosure of persons having ownership, financial, or control interest.

(a) *Information that must be disclosed.* A disclosing entity must submit the following information in the manner specified in paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the entity or in any subcontractor in which the entity has direct or indirect ownership interest totaling 5 percent or more. In the case of a part B supplier that is a joint venture, ownership of 5 percent or more of any

company participating in the joint venture should be reported. Any physician who has been issued a Unique Physician Identification Number by the Medicare program must provide this number.

* * * * *

(3) The name of any other disclosing entity in which any person with an ownership or control interest, or who is a managing employee in the reporting disclosing entity, has, or has had in the previous three-year period, an ownership or control interest or position as managing employee, and the nature of the relationship with the other disclosing entity. If any of these other disclosing entities has been convicted of a criminal offense or received a civil monetary or other administrative sanction related to participation in Medicare, Medicaid, title V (Maternal and Child Health) or title XX (Social Services) programs, such as penalties assessments and exclusions under sections 1128, 1128A or 1128B of the Act, the disclosing entity must also provide that information.

* * * * *

(b) * * *

(2) Any disclosing entity that is not subject to periodic survey and certification must supply the information specified in paragraph (a) of this section to HCFA before entering into a contract or agreement with Medicare or before being issued or reissued a billing number as a part B supplier.

(3) A disclosing entity must furnish updated information to HCFA at intervals between recertification, or re-enrollment, or contract renewals, within 35 days of a written request. In the case of a part B supplier, the supplier must report also within 35 days, on its own initiative, any changes in the information it previously supplied.

(c) *Consequences of failure to disclose.* (1) HCFA does not approve an agreement or contract with, or make a determination of eligibility for, or (in the case of a part B supplier) issue or reissue a billing number to, any disclosing entity that fails to comply with paragraph (b) of this section.

(2) HCFA terminates any existing agreement or contract with, or withdraws a determination of eligibility for or (in the case of a part B supplier) revokes the billing number of, any disclosing entity that fails to comply with paragraph (b) of this section.

* * * * *

C. Part 421 is amended as follows:

PART 421—INTERMEDIARIES AND CARRIERS

1. The authority citation for part 421 is revised to read as follows:

Authority: Secs. 1102, 1815, 1816, 1833, 1834(a) and (h), 1842, 1861(u), 1871, 1874, and 1875 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395h, 1395l, 1395m (a) and (h), 1395u, 1395x(u), 1395hh, 1395kk, and 1395ll), and 42 U.S.C. 1395b–1.

Subpart A—Scope, Definitions, and General Provisions

2. Section 421.1(a) is revised to read as follows:

§ 421.1 Basis and scope.

(a) This part is based on sections 1124A, 1815, 1816, 1834, 1842, and 1874 of the Social Security Act and 42 U.S.C. 13956–1 (experimental authority).

* * * * *

3. In subpart C, § 421.200, the introductory text is revised to read as follows:

Subpart C—Carriers

§ 421.200 Carrier functions.

A contract between HCFA and a carrier, other than a regional DMEPOS carrier, specifies the functions to be performed by the carrier which must include, but are not necessarily limited to, the following:

* * * * *

4. In § 421.202, the introductory text and paragraph (c) are revised to read as follows:

§ 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, HCFA determines that the carrier—

* * * * *

(c) Will be able to meet any other requirements HCFA considers pertinent, and, if designated a regional DMEPOS carrier, any special requirements for regional carriers under § 421.210 of this subpart.

5. New § 421.210 is added to read as follows:

§ 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

(a) *Basis.* This section is based on sections 1834(a) and 1834(h) of the Act which authorize the Secretary to designate one or more carriers by specific regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics and other supplies (DMEPOS). This authority has been delegated to HCFA.

(b) *Types of claims.* Claims for the following, except for items incident to a physician's professional service as defined in § 410.26, incident to a physician's service in a rural health clinic as defined in § 405.2413, or bundled into payment to a provider, ambulatory surgical center, or other facility, are processed by the designated carrier for its designated region and not by other carriers—

(1) Durable medical equipment (and related supplies) as defined in section 1861(n) of the Act;

(2) Prosthetic devices (and related supplies) as described in section 1861(s)(8) of the Act, (including intraocular lenses and parenteral and enteral nutrients, supplies, and equipment, when furnished under the prosthetic device benefit);

(3) Orthotics and prosthetics (and related supplies) as described in section 1861(s)(9);

(4) Home dialysis supplies and equipment as described in section 1861(s)(2)(F);

(5) Surgical dressings and other devices as described in section 1861(s)(5);

(6) Immunosuppressive drugs as described in section 1861(s)(2)(J); and

(7) Other items or services which are designated by HCFA.

(c) *Region designation.* The boundaries of the four regions for processing claims described in paragraph (b) of this section coincide with the boundaries of 1 or more sectors or areas designated for the Common Working File. These four regions contain the following States and territories: Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware. Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wiconsin and Minnesota. Region C: North Carolina, South Carolina, Kentucky, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Arkansas, Oklahoma, New Mexico, Colorado, Puerto Rico and the Virgin Islands. Region D: Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, California, Nevada, Arizona, Washington, Oregon, Montana, Idaho, Utah, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Iowa and Missouri.

(d) *Criteria for designating regional carriers.* HCFA designates regional carriers to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program as measured by—

(1) Timeliness of claim processing;

(2) Cost per claim;
(3) Claim processing quality;
(4) Experience in claim processing, and in establishing local medical review policy; and
(5) Other criteria that HCFA believes to be pertinent.

(e) *Carrier designation.* (1) Each carrier designated a regional carrier is responsible, using the payment rates applicable for the State of residence of a beneficiary, including a qualified Railroad Retirement beneficiary, for processing claims for items listed in paragraph (b) of this section for beneficiaries whose permanent residence is within the area designated in paragraph (c) of this section. A beneficiary's permanent residence is the address at which he or she intends to spend 6 months or more of the calendar year.

(2) The identities of the regional carriers are specified in a notice published in the **Federal Register** when contracts are established.

(f) *Collecting information of ownership.* Carriers designated as regional claims processors must obtain from each supplier of items listed in paragraph (b) of this section information concerning ownership and control as required by section 1124A of the Act and part 420 of this chapter, and certifications that supplier standards are met as required by part 424 of this chapter.

D. Part 424 is amended as set forth below:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 216(j), 1102, 1814, 1815(c), 1835, 1842(b), 1861, 1866(d), 1870 (e) and (f), 1871 and 1872 of the Social Security Act (42 U.S.C. 416(j), 1302, 1395f, 1395g(c), 1395n, 1395u(b), 1395x, 1395cc(d), 1395gg (e) and (f), 1395hh and 1395ii).

2. Section 424.57 is added to subpart D to read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers.

(a) *Definitions.* As used in this section—"DMEPOS" is the acronym for durable medical equipment, prosthetics, orthotics and supplies. A "supplier" is an entity or individual, including a physician or part A provider, which sells or rents part B covered items to Medicare beneficiaries and which meets the standards in paragraph (c) of this section.

(b) Medicare pays for items furnished by a supplier with a billing number to the—
(1) Supplier if the beneficiary (or the person authorized to request payment on the beneficiary's behalf) assigns the claim to the supplier and the supplier accepts assignment;
(2) Beneficiary, if the supplier does not accept assignment; or
(3) Partly to the beneficiary and partly to the supplier, if the supplier accepts assignment of the bill, as described in § 424.56.

(c) Medicare does not issue a billing number to a supplier that submits claims for items listed in § 421.210(b) of this subchapter until that supplier meets, and certifies that it meets, the following standards. The supplier—
(1) In response to orders which it receives, fills those orders from its own inventory or inventory in other companies with which it has contracted to fill such orders or fabricates or fits items for sale from supplies it buys under a contract;
(2) Is responsible for delivery of Medicare covered items to Medicare beneficiaries;
(3) Honors all warranties express and implied under applicable State law;
(4) Answers any questions or complaints a beneficiary has about the item or use of the item that was sold or rented to him or her, and refers beneficiaries with Medicare questions to the appropriate carrier;
(5) Maintains and repairs directly or through a service contract with another company, items it has rented to beneficiaries;
(6) Accepts returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and/or sold) from beneficiaries;
(7) Discloses consumer information to each beneficiary with whom it does business which consists of the supplier standards to which it must conform; and
(8) Complies with the disclosure provisions in § 420.206 of this subchapter.

(d) If a supplier is found not to meet the standards in paragraph (c) of this section, its billing number is revoked, effective 15 days after the entity is sent notice of the revocation. A billing number may be issued, with the concurrence of HCFA, when a supplier has successfully completed a corrective action plan rectifying past violations of the supplier standards and provided sufficient assurance that it will comply with the supplier standards in the future. Corrective action includes repayment of monies due to beneficiaries and Medicare, and honoring applicable warranties.

(e) Suppliers must renew their applications for a billing number 3 years after the billing numbers are first reissued, except for the first reissuance process, as follows: suppliers must renew applications for supplier numbers 2 years after initial issuance of billing numbers for one third of all suppliers. Another one third of suppliers must reapply 3 years after initial issuance. The last third of suppliers must reapply 4 years after initial issuance. Thereafter, each supplier must reapply 3 years after its last number is issued, unless no claim for an item furnished by a supplier has been submitted for four consecutive quarters, in which case the supplier must submit a new request for another billing number.

(f) Suppliers are required to have complaint resolution protocols to address beneficiary complaints which relate to the supplier standards in paragraph (c) of this section and to keep written complaints and related correspondence, and any notes of actions taken in response to written or oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. If a carrier determines that a supplier is not satisfactorily responding to one or more beneficiary complaints, the carrier may require that a supplier maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives: The name, address, telephone number and health insurance claim number of the complaint, a summary of the complaint and the date it was made; the name of the person taking the complaint, a summary of any actions taken to resolve the complaint; and, if an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance and No. 93.774 Supplementary Medical Insurance Program)

Dated: April 28, 1992.

William Toby,

Acting Administrator, Health Care Financing Administration.

Approved: May 6, 1992.

Louis W. Sullivan,

Secretary.

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